COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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Tentative Agenda
Regulation Committee for Drug Diversion and Responsibility of Pharmacist-in-Charge to Provide Adequate Safeguards

November 25, 2013

9 AM

TOPIC	PAGE(S)

Call to Order: Cynthia Warriner, Committee Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda

Call for Public Comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

Items Included in Agenda Packet

- Excerpt of Draft Minutes from September 10, 2013 Full Board Meeting — 1
- Laws and Regulations Relating to Pharmacist-in-Charge — 2-22
- Report of the NABP Task Force on the Control and Accountability of Prescription Medications — 23-34
- Various State Regulations regarding PIC Responsibilities — 35-103
- Guidance Document 110-27 - PIC Responsibilities — 104-106
- Application for a Pharmacy Permit — 107-108

The meeting will adjourn at approximately 11am, prior to the start of the Ad Hoc Committee meeting scheduled to begin at 11am.

template is being utilized that was established by a past committee. A goal is to streamline collected data so it is comparable across professions. Mr. Crowe reviewed the handouts with the Board and stated that comments may be received until September 25, 2013.

STAFF REQUEST TO CONVENE AD HOC INSPECTION COMMITTEE TO REVIEW GUIDANCE DOCUMENT 110-9 AND DEVELOP SIMILAR GUIDANCE FOR INSPECTIONS OF PHYSICIAN SELLING DRUGS:

Staff indicated that the routine pharmacy inspection process has been in use for three years and that it may be an appropriate time to thoroughly review Guidance Document 110-9 regarding suggested monetary penalties resulting from routine pharmacy inspections. Additionally, staff suggested that the Board consider developing similar guidance for inspections of physician selling drugs locations as a means of expediting the possible disciplinary action resulting from the increased number of physicians licensed to sell drugs.

MOTION:

The Board voted unanimously to convene the ad hoc committee to review Guidance Document 110-9 and consider the development of similar guidance for the routine inspections of physicians licensed to sell drugs. (motion Rhodes, second Kozera)

BOARD MEMBER REQUEST TO DISCUSS POSSIBLE DISCIPLINARY ACTION AGAINST PICS FOLLOWING DOCUMENTED LOSS OF CONTROLLED SUBSTANCES:

Mr. Adams distributed a handout (Attachment 2) that supported his concerns regarding the documented losses of controlled substances within a pharmacy and that the pharmacist-in-charge (PIC) should be held accountable for that loss. Mr. Adams stated that during his research, he discovered that in the first six months of the year 2013, only nine disciplinary actions, resulting from drug losses, were taken against a PIC. The document outlined sections of law and regulation identified by Mr. Adams which he stated supports the pharmacist's responsibility to appropriately secure controlled substances.

MOTION:

The pharmacist-in-charge (PIC) of a pharmacy that experiences either diversion or theft of Schedule II-VI drugs exceeding 100 oral tablets, or 100 usual oral liquid doses, or 25 ampules or vials shall be in violation of:

1. **18 VAC 110-20-25(6) Unprofessional Conduct: Failure to maintain adequate safe guards against diversion of controlled substances and,**
2. **Section 54.1-3434: Failure to provide safeguards against diversion of all controlled substances and,**
3. **18VAC 110-20-110(B) Pharmacy Permits: Failure to control all aspects of the practice of pharmacy and,**
4. **Section 54.1-3432: Failure to supervise the pharmacy and its personnel. The PIC shall be fined a minimum of $250 up to $5,000 and reprimanded. (motion by Adams, second by Stelly, 8 opposed, motion defeated)**

MOTION:

The Board voted unanimously to refer Mr. Adam's concerns for drug diversion and PIC accountability to the Regulation Committee for further research and to determine the best course of action. (motion by Stelly, second by Rhodes)

Law and Regulation relating to "Pharmacist-in- Charge"

Code of Virginia

§ 54.1-3401. Definitions.

"**Pharmacist-in-charge**" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

K. Every **pharmacist-in-charge** or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

The **pharmacist-in-charge** at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no product shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured.

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a **pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.**

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to **the pharmacist-in-charge** practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a

conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the **pharmacist-in-charge** to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the **pharmacist-in-charge** and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the **pharmacist-in-charge**, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the **pharmacist-in-charge** to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new **pharmacist-in-charge**. At the conclusion of the time period for designation of a new **pharmacist-in-charge**, a pharmacy which has failed to designate a new **pharmacist-in-charge** shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding **pharmacist-in-charge** shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes **pharmacist-in-charge** and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.02. Automated drug dispensing systems.

A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;

2. The **pharmacist-in-charge** of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the **pharmacist-in-charge** of a pharmacy located within the hospital or the **pharmacist-in-charge** of any outside pharmacy providing pharmacy services to the hospital;

6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the **pharmacist-in-charge**. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug

dispensing system or the **pharmacist-in-charge**, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.

B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved by the **pharmacist-in-charge** in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.

C. The **pharmacist-in-charge** in a pharmacy located within a hospital or the **pharmacist-in-charge** of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the **pharmacist-in-charge's** procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.

18VAC110-20-10. Definitions.

"**PIC**" means the **pharmacist-in-charge** of a permitted pharmacy.

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

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.

C. When the **PIC** ceases practice at a pharmacy or no longer wishes to be designated as **PIC**, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the **PIC**.

D. Although not required by law or regulation, an outgoing **PIC** shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the **PIC**, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. A **PIC** who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the **PIC**. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the **PIC**, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new **PIC**.

F. An application for a permit designating the new **PIC** shall be filed with the required fee within 14 days of the original date of resignation or termination of the **PIC** on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-25. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the **PIC** to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; or

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing.

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

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.

C. When the **PIC** ceases practice at a pharmacy or no longer wishes to be designated as **PIC**, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

D. Although not required by law or regulation, an outgoing **PIC** shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the **PIC**, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. A **PIC** who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the **PIC**. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the **PIC**, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new **PIC**.

F. An application for a permit designating the new **PIC** shall be filed with the required fee within 14 days of the original date of resignation or termination of the **PIC** on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-120. Special or limited-use pharmacy permits.

A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.

2. The **PIC** shall be notified prior to each entry and give permission for the designated, specific individuals to enter.

3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.

4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The **PIC** shall ensure that the alarm access code is changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the **pharmacist-in-charge** and the date it was granted. Such log shall be maintained on premises for one year.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.

A. At least 14 days prior to the date a pharmacy closes in accordance with §54.1-3434.01 of the Code of Virginia or goes out of business, the owner shall notify the board. The proposed disposition of all Schedule II through VI drugs, prescription dispensing records, patient information records, and other required records shall be reported to the board. If the pharmacy drug stock and records are to be transferred to another licensee, the owner shall inform the board of the name and address of the licensee to whom the drugs and records are being transferred and the date of transfer. Prescription records for prescriptions with active refills shall be transferred

to another pharmacy where a patient may obtain access for the purpose of obtaining refills either at that location or in accordance with the transfer provisions of 18VAC110-20-360.

B. Exceptions to the public notice as required in §54.1-3434.01 of the Code of Virginia and the notice required in subsection A of this section shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmacy is not able to meet the notification requirements of § 54.1-3434.01, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

C. In the event of an exception to the notice as required in §54.1-3434.01 of the Code of Virginia and in subsection A of this section, the **PIC** or owner shall provide notice as far in advance of closing as allowed by the circumstances.

D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmacy, the prescription dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of pharmacy services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

3. The format of the prescription dispensing records which are transferred to a new owner shall comply with the requirements of Chapter 34 (§54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, and this chapter. Failure to comply with this chapter during a change in ownership shall be deemed to be a closing of the existing pharmacy for which the existing pharmacy owner shall be required to provide notice to the board and public in accordance with §54.1-3434.01 of the Code of Virginia and subsection A of this section.

18VAC110-20-170. Required minimum equipment or resources.

The **PIC** shall be responsible for maintaining the following:

1. A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy.

2. A set of Prescription Balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components.

3. Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety.

18VAC110-20-180. Security system.

A. A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

B. Exceptions to provisions in this section:

1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, 2, and 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

3. This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the **PIC** or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, a security system that meets the requirements of subdivisions A 1 through 4 of this section.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.

2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.

3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the **PIC** with the following exceptions:

1. The **PIC** or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the **PIC** or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Altemate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration; and

4. All requirements of subsection E of this section are met.

E. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the **PIC** or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the **PIC** shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

18VAC110-20-210. Disposal of drugs by pharmacies.

If a **PIC** wishes to dispose of unwanted drugs, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or

2. Destroy the drugs by burning in an incinerator, or other board-approved method, in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, the following procedures shall apply:

a. At least 14 days prior to the destruction date, the **PIC** shall provide a written notice to the board office; the notice shall state the following:

(1) Date, time, manner, and place of destruction.

(2) The names of the pharmacists who will witness the destruction process.

b. If the destruction date is to be changed or the destruction does not occur, a new notice shall be provided to the board office as set forth above in subdivision 2 of this section.

c. The actual destruction shall be witnessed by the **PIC** and another pharmacist not employed by the pharmacy.

d. The DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the pharmacy with other inventory records.

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.

A. The **PIC** in a pharmacy located within a hospital or the **PIC** of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The **PIC** of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the **PIC** shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the **PIC** of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to non-pharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the **PIC** assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;

2. Irrigation solutions;

3. Contrast media;

4. Medical gases;

5. Sterile sealed surgical trays that may include a Schedule VI drug; and

6. Blood components and derivatives, and synthetic blood components and products.

18VAC110-20-450. After-hours access to the pharmacy.

A. When authorized by the **PIC**, an authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, provided that such drug is available in the

manufacturer's original package or in units which have been prepared and labeled by a pharmacist and provided further that a separate record shall be made and left at the location of the stock of drugs on a form prescribed by the **PIC** and such records are maintained within the pharmacy for a period of one year showing:

1 The date of withdrawal;

2. The patient's name;

3. The name of the drug, strength, dosage form and dose prescribed;

4. Number of doses removed; and

5. The signature of the authorized nurse.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The **PIC** or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the **PIC** and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the practitioner.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

3. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. The **PIC** or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the **PIC** or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

5. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

6. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

7. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

8. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

9. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and

review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the **PIC** and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The **PIC** of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

5. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

6. At the direction of the **PIC**, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

7. At the time of loading, the delivery record for all Schedule II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

8. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the **PIC**, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

9. The **PIC** or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the **PIC** or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

12. The **PIC** of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

13. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Report of the Task Force on the Control and Accountability of Prescription Medications

Members Present:

John Clay Kirtley (AR), *chair;* Herb Bobo (AL); William Fitzpatrick (MO); Virginia Herold (CA); Gary Karel (SD); Douglas R. Lang (MO); Alice Mendoza (TX); Leo Richardson (SC); and Joanne Trifone (MA).

Others Present:

Edward G. McGinley, *Executive Committee liaison*; Carmen Catizone, Melissa Madigan, Eileen Lewalski, Deborah Zak, *NABP staff.*

Introduction:

The Task Force on the Control and Accountability of Prescription Medications met October 26-27, 2011, at NABP Headquarters. This task force was established in response to Resolution 107-3-11, Control and Accountability of Prescription Medications, which was approved by the NABP membership at the Association's 107th Annual Meeting in May 2011.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing state laws and regulations addressing the control and accountability of prescription drugs, the Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act, as well as relevant sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act).*
2. Recommend revisions, if necessary, to the *Model Act* addressing this issue.

Recommendation 1: NABP Should Amend the *Model Act*

The task force recommends the following changes to the *Model Act*, including changes to the Model Rules for the Practice of Pharmacy. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

Article III

Licensing

Section 302. Qualifications for Licensure by Examination.

(a) To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:

(1) have submitted a written application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) be of good moral character;
(4) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;
(5) have graduated from a foreign college of Pharmacy, completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication-ability testing as defined under Board of Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;
(6) have completed a Pharmacy practice experience program or other program that has been approved by the Board of Pharmacy, or demonstrated to the Board's satisfaction that experience in the Practice of Pharmacy which meets or exceeds the minimum Pharmacy practice experience requirements of the Board;
(7) have successfully passed an examination or examinations given by the Board of Pharmacy;
(8) have undergone a state and federal fingerprint-based criminal background check; and
(9) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the license.

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Section 305. Renewal of Licenses and Registrations.

(a) Each Pharmacist and Pharmacy Intern shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician who desires to continue or assist in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee, has continued his or her Pharmacy education, if required, in accordance with the rules of the Board, and is entitled to continue in or assist in the Practice of Pharmacy, the Board shall issue a license to the applicant.

...

(c) A Pharmacist shall apply for renewal of his or her registration to Practice Telepharmacy Across State Lines annually [or at such interval determined by the Board], no later than the first day of (month). A Pharmacist who desires to continue in the Practice of Telepharmacy Across State Lines shall file with the Board an application in such form

and containing such data as the Board may require for renewal of the registration. If the Board finds that the applicant has been licensed to Practice Pharmacy in another State and registered to Practice Telepharmacy Across State Lines in this State, that such license and registration have not been Revoked or placed under Suspension, and that the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee and is entitled to continue to engage in the Practice of Telepharmacy Across State Lines, the Board shall issue a registration to the applicant.

Section 302(a)(8). Comment.

If the applicant does not complete the application process within a period specified by the Board, it is recommended that the state and federal fingerprint-based criminal background check be repeated.

Section 308. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:

(1) have submitted a written application in the form prescribed by the Board of Pharmacy;

(2) have attained the age of _____;

(3) have good moral character;

(4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;

(5) have:

(i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy; or

(ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy;

(6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;

(7) have undergone a state and federal fingerprint-based criminal background check; and

(8) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

Section 309. Registration of Pharmacy Technicians.

(a) In order to be registered as a Pharmacy Technician in this State, an applicant shall:
(1) have submitted a written application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;
(3) have good moral character;
(4) have undergone a state and federal fingerprint-based criminal background check;
(5) have paid the fees specified by the Board; and
(6) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Pharmacy Technician.

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Pharmacy Technicians.

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Section 308(b) and 309(b). Comment.

The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Pharmacy Technician under terms and conditions deemed appropriate. ~~The state may decide to perform a criminal background check on individuals seeking to register as Certified Pharmacy Technicians or Pharmacy Technicians.~~

...

Article V

Licensing of Facilities

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board:
(1) persons engaged in the Practice of Pharmacy;
(2) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
(3) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and
(4) pharmacy Benefits Managers.
Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification. The Board shall adopt definitions in addition to those provided in Article I, Section 105,

where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.

(c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

...

(f) The Board of Pharmacy may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(g) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V and shall ~~determine those facilities that~~ require initial inspections and periodic inspections thereafter for purposes of licensure or licensure renewal.

...

Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:

(1) permanent closing;
(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
(3) any theft or loss of Drugs or Devices;
(4) any conviction of any employee of any State or Federal Drug laws;
(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel
(6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
(7) occurrences of Significant Adverse Drug Reactions as defined by Rules of the Board;
(8) illegal use or disclosure of Protected Health Information; or
(9) any and all other matters and occurrences as the Board may require by rule.

...

Model Rules for the Practice of Pharmacy

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:

(1) have submitted a written application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) be of good moral character;
(4) have undergone a state and federal fingerprint-based criminal background check;
(5) have undergone a Pharmacy inspection by the Board; and
(6) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) Minimum requirements for a Pharmacy:

(1) Each Pharmacy shall be of sufficient size to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

...

(8) Security.

(i) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.

(ii) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use. Locks and access codes shall be changed in the event of separation of employment of an employee due to any suspected or confirmed Drug-related reason, including diversion, or other acts involving dishonesty.

...

Section 2. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:

...

(C) policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern. Quality assurance programs shall be designed to prevent and detect Drug diversion.

...

(iii) Notifying the Board of Pharmacy immediately of any of the following changes:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Pharmacy Technician, or Certified Pharmacy Technician for any suspected or confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder ~~or other Person in charge of the Pharmacy~~ shall notify the Board of Pharmacy;

(C) change of ownership of the Pharmacy;
(D) change of address of the Pharmacy; or
(E) permanent closing of the Pharmacy.

(iv) Making or filing any reports required by State or Federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.

(5) The Pharmacist-in-Charge of a Pharmacy that ships medications by mail or common carrier shall be responsible for the development and implementation of a policies and procedures to:

a. properly transfer prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;
b. require common carrier to conduct criminal background checks and random drug screens on its employees who have access to prescription medications; and
c. track all shipments.

...

(c) If any action of the Pharmacy is deemed to contribute to or cause a violation of any provision of this section, the Board may hold the owner and/or Pharmacy permit holder responsible and/or absolve the Pharmacist-in-Charge from the responsibility of that action.

Section 2(a)(2)(i)(C). Comment

As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge is encouraged to ensure polices and procedures are in place that address the following:

- inspection of shipments;
- receipt verification oversight and checking in shipments;
- reconciliation of orders;
- inventory management including:
  - determination of Medications that need to be monitored and controlled beyond existing systems such as controlled substances and drugs of concern; and
  - conducting quarterly reconciliations at a minimum but shall be more frequent up to perpetual, depending on the potential for or incidence of diversion for a particular drug.

The Pharmacist-in-Charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following:

- periodic reviews of employee access to any secure controlled substance storage areas, which may include:
  - alarm codes and lock combinations;
  - passwords;
  - keys and access badges; and
  - video surveillance systems.

Section 2(a)(32)(iii). Comment.

If states require the Pharmacist-in-Charge or other Person in charge of the Pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of Drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting Pharmacy.

In instances where the Pharmacist-in-Charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the Person in charge, then the Board must take action to cease operation of the Pharmacy.

Boards of pharmacy are strongly encouraged to require that pharmacy owners and/or permit holders have policies and procedures in place to conduct initial and random drug screenings of all employees that have access to prescription drugs including controlled substances.

Model Rules for Pharmacy Interns

Section 1. Licensure.

Every individual shall be licensed by the Board of Pharmacy before beginning Pharmacy practice experiences in this State. A license to practice Pharmacy as a Pharmacy Intern shall be granted only to those individuals who:

(a) are enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(b) are graduates of an approved professional degree program of a school or college of Pharmacy or are graduates who have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who are currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

(c) are qualified applicants awaiting examination for licensure or meeting Board requirements for re-licensure; or

(d) are participating in a residency or fellowship program; and

(e) have undergone a state and federal fingerprint-based criminal background check.

...

Background:

The task force identified and discussed at length the serious and growing concern of drug diversion in pharmacies. The task force proposed revisions to the *NABP Model Act* to address

some of the immediate concerns presently occurring and endangering the public health. Of particular concern is the increased incidence of pharmacy personnel, especially unlicensed or unregistered staff, having access to prescription medications, including controlled substances, and diverting them through various means to themselves or the public. Members voiced concern that security and inventory control provisions, including the ordering and receiving of controlled substances, lacked specific safeguards to prevent diversion and as such recommended that the pharmacist provide additional oversight as well as requiring the pharmacist to perform certain inventory functions including the reconciliation of orders. Along those lines, members also agreed that criminal background checks should be required for all pharmacy owners and/or pharmacy permit holders, pharmacy staff, including pharmacists, pharmacy technicians, pharmacy interns, and any other staff that has access to prescription medications, including controlled substances as a first approach to prevent against diversion.

Recommendation 2: NABP Should Encourage Boards of Pharmacy to Incorporate Existing Model Act Language Pertaining to the Reporting of Separation of Employment for Suspected or Confirmed Drug-Related Reasons

The task force recommends that NABP encourage the boards of pharmacy to incorporate, if they have yet to do so, existing *Model Act* language pertaining to the reporting of separation of employment of any pharmacist, pharmacy intern, pharmacy technician, or certified pharmacy technician for any suspected or confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination.

Background:

The task force expressed the concern that licensees, particularly pharmacy technicians, can easily obtain new employment after being terminated or having resigned from a pharmacy due to a drug-related incident such as suspected or confirmed abuse, theft, or diversion of drugs. Members agreed that this behavior could be prevented and the risk of diversion decreased, if these types of incidences were reported to the boards so that appropriate disciplinary action could be taken to ensure that these individuals would no longer have access to prescription drugs, including controlled substances.

Recommendation 3: NABP Should Recommend that Colleges and Schools of Pharmacy Increase the Emphasis on Ethical and Legal Responsibilities Related to the Position of Pharmacist-in-Charge

The task force recommends that NABP recommend to colleges and schools of pharmacy to increase the emphasis on the ethical and legal responsibilities related to the pharmacist-in-charge (PIC) position during relevant pharmacy law or pharmacy management courses.

Background:

The task force discussed the increased prevalence of newly graduated pharmacists accepting PIC positions and the fact that many were being called in before the boards for reasons indicating a lack of knowledge and awareness about the duties and responsibilities of being a PIC. Members decided that providing this information to pharmacy students in the pharmacy law or pharmacy management class would better prepare pharmacists to capably assume PIC positions or at the

very least impress on students that being a PIC is a major responsibility and perhaps gaining some experience before undertaking such a role is prudent.

Recommendation 4: NABP Should Encourage Boards of Pharmacy to Require Continuing Education for Pharmacists-in-Charge Pertaining to Legal Responsibilities of this Position

The task force recommends that NABP encourage state boards of pharmacy to require PICs to complete at least three hours of continuing education every renewal period detailing the additional legal duties and responsibilities of the PIC position.

Background:

The task force noted that all PICs assume a legal responsibility to manage the pharmacy and practice in a safe and secure manner. As previously mentioned the task force noted that many PICs are newly graduated and licensed and assume the legal responsibilities of this position without being adequately prepared or having an understanding of what is at stake. The task force recommended that NABP encourage boards of pharmacy to require continuing education programs for PICs addressing their legal responsibilities, including diversion prevention, and suggest that they be no less than a total of three hours in duration per renewal period.

Recommendation 5: NABP Should Encourage Pharmacy Associations and Employers to Develop Educational and Training Programs Focusing on the Ethical and Legal Responsibilities of the Pharmacist-in-Charge

The task force recommends that NABP encourage pharmacy associations and employers to develop educational and training programs that focus on the ethical and legal responsibilities of the PIC.

Background:

The task force again expressed concern over the lack of education and training for PICs and determined that a multi-faceted approach would best suit this necessity. Members also discussed the ethical dilemmas that many PICs face and the need for this issue to be addressed appears to be more important in today's society. Members agreed that training on ethical and legal responsibilities should begin in pharmacy school and continue throughout a pharmacist's career.

Recommendation 6: NABP Should Strongly Encourage Pharmacy Employers to Conduct Initial and Random Drug Screening on All Employees Who Have Access to Prescription Drugs and to Require Common Carriers Utilized by the Pharmacy to Deliver Patient Prescriptions to Conduct Such Drug Screenings on their Employees

The task force recommends that NABP strongly encourage pharmacy employers to conduct initial and random drug screens on all employees who have access to prescription drugs and to require any common carriers utilized by the pharmacy to deliver prescriptions to their patients to conduct initial and random drug screens on their employees.

Background:

The task force emphasized the important role that initial and random drug screens play in the deterrence of employee theft and diversion and agreed that both boards of pharmacy and employers should require them. Members discussed various methods of conducting drug screens,

such as an employer requiring employees to provide urine samples during their shift so as to prevent any tampering, and determined that drug screening was an extremely powerful and effective tool in discovering and preventing diversion.

Recommendation 7: NABP Should Develop Resources and Programs to Assist Boards of Pharmacy in Educating and Assisting Pharmacists and PICs Regarding their Legal Responsibilities to Maintain Security and Prevent Drug Diversion

The task force recommends that NABP develop resources and programs that will assist boards of pharmacy in educating and assisting pharmacists, particularly PICs, to understand their legal responsibilities and how to properly execute them in order to maintain pharmacy security and prevent employee theft and drug diversion.

Background:

The task force conveyed many anecdotal accounts of "victims" of diversions in which the PIC had absolutely no idea that inventory was being compromised and controlled substances were being diverted, sometimes by the supposedly least likely person. Members agreed that providing a "tool box" of strategies for boards to assist pharmacists and PICs in preventing diversion was a good proactive approach. Such tools for boards could include continuing education or continuing professional development programs or an assessment tool for determining PIC competence (which could be administered "open book" if so desired by the board). Such tools for pharmacists and PICs could include model policies and procedures, recommendations regarding employee access to paper and electronic records, recommendations regarding physical access to prescription drugs, information on how to determine which drugs should be reconciled by perpetual inventory and how to implement such, how to conduct an audit, utilizing in and out reporting, implementing individualized ordering, staff warning signs, and real life case studies that PICs can utilize as teaching aids.

Recommendation 8: NABP Should Request Harmonization of Qualifications for Entry into Colleges and Schools of Pharmacy and Pharmacy Technician Education Programs

The task force recommends that NABP work with the American Association of Colleges of Pharmacy (AACP), the Accreditation Council for Pharmacy Education, and other interested stakeholders to harmonize the entry qualifications for colleges and schools of pharmacy and pharmacy technician education programs so as to prohibit the admission of those individuals who would never qualify for licensure.

Background:

The task force noted the ongoing and increasing problem of the admission of individuals into pharmacy schools and colleges as well as pharmacy technician education programs absent a background check and other inquiries that would identify reasons that would prohibit an individual from being granted licensure/registration. Members discussed instances in which upon an individual's application for a pharmacy intern license, a past offense that would bar that individual from ever being granted a pharmacist license is discovered. Members also discussed the bevy of pharmacy technician schools that entice individuals to complete their programs without ever explaining to them that certain convictions or arrests will make it impossible for them to ever become licensed or registered. It was suggested that perhaps educational programs

should utilize the same background questions as the boards of pharmacy on their applications for admission to ensure consistency in the information received.

Recommendation 9: NABP Should Encourage the NABP/AACP District Meeting Chairs to Include the Topics of Drug Diversion and Prescription Drug Abuse in the Programming for Joint Sessions with the Boards and Colleges and Schools of Pharmacy

The task force recommends that NABP encourage the district meeting chairs to include in the programming the topics of drug diversion and prescription drug abuse for the boards and colleges and schools of pharmacy joint sessions and consider inviting a representative from the US Drug Enforcement Administration to speak on this topic.

Background:

Members again stressed the importance of education and agreed that it should be a multi-faceted approach, whereby boards and colleges and schools of pharmacy should coordinate their efforts to emphasize the importance of being aware of the incidence of drug diversion and how to prevent it.

Recommendation 10: NABP Should Issue a Statement of Concern Regarding Drug Diversion and Prescription Drug Abuse that Incorporates the AWAR$_X$E Program

The task force recommends that NABP issue a public statement denoting the problem and the immediate need to address and encourage other stakeholders to take a proactive role in combating drug diversion and prescription drug abuse that incorporates the AWAR$_X$E program.

Background:

The task force strongly agreed that the pervasiveness of drug diversion and prescription drug abuse are significant concerns and endanger the public health. Prescription drug abuse is the primary source of death in 17 states as indicated by statistics overshadowing automobile accidents and gunshot incidents. NABP staff provided information on the AWAR$_X$E program and its various tools for boards of pharmacy, pharmacists, and patients alike to assist them in becoming aware of drug abuse and what they can do to prevent its incidence. Members adamantly concurred that this serious issue is epidemic in nature and recommended that NABP take swift and decisive steps to curb this trend.

"PIC Responsibilities — Theft, Diversion, Controlled Substances"

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Alaska

/ALASKA/ALASKA Board of Pharmacy Regulations/AK BReg Title 12. Professional and Vocational Regulations/AK BReg Chapter 52. Board of Pharmacy Regulations /AK BReg Article 2. Personnel/AK BReg 12 AAC 52.200. Pharmacist-in-charge.

AK BReg 12 AAC 52.200.
Pharmacist-in-charge.

(a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation.

History: (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177)

NABP*LAW* 10/2013

/ALASKA/ALASKA Board of Pharmacy Regulations/AK BReg Title 12. Professional and Vocational Regulations/AK BReg Chapter 52. Board of Pharmacy Regulations /AK BReg

/ALASKA/ALASKA Board of Pharmacy Regulations/AK BReg Title 12. Professional and Vocational Regulations/AK BReg Chapter 52. Board of Pharmacy Regulations /AK BReg Article 5. Pharmacy practice standards./AK BReg 12 AAC 52.540. Notification of theft or significant loss.

AK BReg 12 AAC 52.540.
Notification of theft or significant loss.

If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.
History: (Eff. 1/16/98, Register 145)

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/ALASKA/ALASKA Board of Pharmacy Regulations/AK BReg Title 12. Professional and Vocational Regulations/AK BReg Chapter 52. Board of Pharmacy Regulations /AK BReg Article 10. Disciplinary guidelines./AK BReg 12 AAC 52.920. Disciplinary guidelines.

AK BReg 12 AAC 52.920.
Disciplinary guidelines.

(a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;

(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making a false or fraudulent claim concerning a drug;

(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;

(12) violating the provisions of a board order or memorandum of agreement;

(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;

(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;

(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;

(18) violating AS 08.80.315 dealing with the confidentiality of records;

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;

(20) offering, giving, soliciting, or receiving compensation for referral of a patient; or

(21) violating AS 08.80.261(a)(3).

(b) The board will, in its discretion, revoke a license if the licensee

(1) commits a violation that is a second offense;

(2) violates the terms of probation from a previous offense;

(3) violates AS 08.80.261(a)(1) or (4);

(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;

(5) is professionally incompetent if the incompetence results in risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee

(1) wilfully or repeatedly violates AS 08.80 or this chapter; or

(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

History: (Eff. 1/16/98, Register 145)

NABP*LAW* 10/2013

Arkansas

/ARKANSAS/ARKANSAS STATE BOARD OF PHARMACY REGULATIONS/AR BReg Title 070. Board of Pharmacy. Division 00. /AR BReg Rule 4. Pharmacy/AR BReg 04-00: General Regulations Regarding Pharmacies/AR BReg 04-00-0010. Pharmacist in Charge.

AR BReg 04-00-0010.
Pharmacist in Charge.

(a) When a pharmacist ceases to be employed as a pharmacist in charge (PIC) at a pharmacy licensed by the Board, the pharmacist must immediately notify the Board in writing. The former PIC must provide an inventory of controlled drugs as defined in Regulation 04-00-0013 to the Board within five days of ceasing employment as the PIC.

(b) When a pharmacist in charge ceases to be employed in that position, the pharmacy permit holder must submit the permit issued in the name of the former PIC to the Board within five days.

(c) The pharmacist in charge is responsible for the security and accountability of all drugs stored in a pharmacy and is responsible for the validity and legality of all prescriptions and/or orders upon which drugs are dispensed in a pharmacy. The pharmacist in charge is responsible for ensuring that pharmacy staff has been appropriately trained to follow the pharmacy's policies and procedures.

(d) Any pharmacist, when making his or her initial application to be licensed as pharmacist in charge, must satisfactorily complete a test on the requirements and responsibilities of a pharmacist in charge. The test shall be developed and administered by the Board of Pharmacy or its representatives.

(e) The pharmacist in charge named on any licensed pharmacy permit or pharmacist on call as designated by the pharmacist in charge, shall have immediate access to the pharmacy at all times, and if requested by Board of Pharmacy inspectors he/she shall show satisfactory proof of access.

(f) If the pharmacy fails to have on staff a licensed pharmacist acting as the pharmacist in charge due to extended illness, death, resignation, or for any other reason, the pharmacy permit holder shall notify the board within five (5) days and must within thirty (30) days, or such additional time at the discretion of the board, either:

(1) Secure the services of an Arkansas-licensed pharmacist to serve as the pharmacist in charge; or

(2) Cease to operate as a pharmacy in the State of Arkansas. Operation of the pharmacy without a pharmacist in charge beyond the time limits set by the Board is a violation of law and each day so operated will be a separate offense.

History: Emergency amendment Apr. 2001; Amended Mar. 14, 2007; Amended Nov. 6, 2008. Amended Nov. 30, 2010.

NABP*LAW* 09/2013

/ARKANSAS/ARKANSAS STATE BOARD OF PHARMACY REGULATIONS/AR BReg Title 070. Board of Pharmacy. Division 00. /AR BReg Rule 4. Pharmacy/AR BReg 04-00:

General Regulations Regarding Pharmacies/AR BReg 070.00.4-04-00-0015. Responsibility for Security of Controlled Drugs

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AR BReg 070.00.4-04-00-0015.
Responsibility for Security of Controlled Drugs

(a) The permit holder and the pharmacist in charge are jointly responsible for the security and accountability of all controlled drugs stored in and/or ordered by a pharmacy.

(b) The permit holder shall provide diversion prevention and detection tools appropriate for the particular pharmacy setting and the pharmacist in charge shall implement and monitor the diversion control and detection tools provided by the permit holder. Appropriate tools may include perpetual inventory, automatic or limited-access online ordering, reports comparing drugs ordered v. drugs dispensed and drugs manually ordered or adjusted, and individual passwords for each employee to enter the pharmacy or access the computer.

(c) The pharmacist in charge and the permit holder shall also develop policies and procedures to prevent and detect diversion and the pharmacist in charge shall ensure that pharmacy staff is trained to follow the policies and procedures. Appropriate policies and procedures may include limiting access by non-pharmacists to controlled drug shipments, performing quarterly audits on high risk drugs, confirming pill count before opening a new bottle of high risk drugs, tracking pill count on stock bottles and requiring staff to use the tools provided by the permit holder.

(d) Pharmacists, pharmacy interns and pharmacy technicians shall implement the tools provided by the permit holder and follow the pharmacy's policies and procedures as instructed by the pharmacist in charge.

History: Adopted Nov. 30, 2010.

NABP*LAW* 09/2013

Colorado

/COLORADO/COLORADO State Board of Pharmacy Rules and Regulations/CO BReg Title 700. Department of Regulatory Agencies/CO BReg 719. State Board of Pharmacy/CO BReg 719-1. State Board of Pharmacy Rules/CO BReg 7.00.00. Pharmacy Manager Responsibilties/CO BReg 7.00.10. Reporting Violations.

CO BReg 7.00.10.
Reporting Violations.

The pharmacist manager of a prescription drug outlet shall report to the Board, in writing, within the timelines set forth in the relevant rules and statutes, the following violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act:

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a. Diversion of substances from the pharmacy.

b. Security breaches within the pharmacy or pharmacy area of the establishment.

c. The unaccountable loss of medications from the pharmacy, whether by theft or unknown means.

d. Any pharmacist working in the pharmacy who is impaired due to the use of alcohol or drugs, or a pharmacist with a mental or physical impairment which affects his ability to perform his job competently. In such instance the report shall be submitted to the Board immediately upon discovery.

e. Significant errors related to the practice of pharmacy, including those related to compounding, such as those that result in serious personal injury or death of a patient. In such instance the report shall be submitted to the Board immediately upon discovery.
History: Amended Jan. 1, 2013.

NABP*LAW* 09/2013

District of Columbia

/DISTRICT OF COLUMBIA/DISTRICT OF COLUMBIA Board of Pharmacy Regulations/DC BReg Title 22. Health./DC BReg Subtitle B. Public Health and Medicine/DC BReg Chapter B19. Pharmacies./DC BReg 1920. PHARMACIST-IN-CHARGE

DC BReg 1920.
PHARMACIST-IN-CHARGE

1920.1 A retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy shall be managed by a pharmacist (hereafter referred to as "Pharmacist-in-charge"). The pharmacist-in-charge shall be licensed to practice pharmacy in the District of Columbia, except that the pharmacist-in-charge of a non-resident pharmacy shall be licensed in the state in which the pharmacy is located.
1920.2 A pharmacist may not serve as a pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as a pharmacist-in-charge for more than one (1) pharmacy at a time except upon obtaining written permission from the Director.
1920.3 In addition to any other responsibilities set forth under this Title, the pharmacist-in-charge or proprietor of a pharmacy shall have the following responsibilities:

(a) Ensuring that quality assurance programs are in place for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient

care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;

(b) Developing or adopting, implementing, and maintaining a training manual and program for the training of all individuals employed in the pharmacy who are legally authorized to assist in the practice of pharmacy. The pharmacist-in-charge shall be responsible for supervising the training program;

(c) Developing or ensuring the establishment of policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

(d) Developing or ensuring the establishment of policies and procedures for the provision of pharmacy services;

(e) Ensuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(f) Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures;

(g) Ensuring that all pharmacists employed at the pharmacy are currently licensed in the District of Columbia, or if it is a non-resident pharmacy, in the state in which the pharmacy is located;

(h) Ensuring that all pharmacy interns employed at the pharmacy are currently registered in the District of Columbia;

(i) Ensuring the making or filing any reports required by federal or District of Columbia laws or regulations, which shall include but not be limited to, notifying the Director of the occurrence of any of the following:

(1) Permanent closing;

(2) Change of proprietorship, management, location, or pharmacist-in-charge;

(3) Any theft or loss of prescription drugs or medical devices;

(4) Conviction of any employee of any federal, state, or District of Columbia drug laws;

(5) Disasters, accidents, or any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;

(6) Occurrences of significant adverse drug reactions;

(7) Illegal use or disclosure of protected patient health information;

(j) Developing or ensuring the establishment of policies and procedures for preventing the illegal use or disclosure of protected health information, or verifying the existences thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established polices and procedures; and

(k) Developing or ensuring the establishment of a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed.

1920.4 The pharmacist-in-charge may be assisted by a sufficient number of pharmacists, pharmacy interns, and pharmacy technicians as may be required to competently and safely provide pharmacy services.

1920.5 The pharmacist-in-charge or proprietor of a pharmacy shall assure the development and implementation of written policies and procedures to specify the duties to be performed by pharmacy interns and pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum:

(a) Specify that pharmacy interns and pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of the pharmacy interns and pharmacy technicians; and

(b) Specify that pharmacy interns and pharmacy technicians shall not be assigned duties that may be performed only by a pharmacist, which shall include but not be limited to:

(1) Drug utilization review;

(2) Clinical conflict resolution;

(3) Prescriber contact concerning prescription drug order clarification;

(4) Patient counseling on prescription, over-the-counter, and herbal products;

(5) Dispensing process validation;

(6) Receiving new oral prescription drug orders, or refill authorizations;

(7) Prescription transfers; and

(8) Independent compounding.

History: Adopted at 38 DCR 6734, 6752 Nov. 8, 1991; Amended at 55 DCR 270 Jan. 11, 2008.

NABP*LAW* 08/2013

Florida

/FLORIDA/FLORIDA Pharmacy Practice Act/FL PracAct Title XXXII. Chapter 465. Pharmacy/FL PracAct 465.022. Pharmacies; General Requirements; Fees.

FL PracAct 465.022.
Pharmacies; General Requirements; Fees.

. . .

(11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(a) The prescription department manager of a permittee must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

(b) The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.

(c) A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

(12) The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a) All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b) The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

(13) Permits issued by the department are not transferable.

(14) The board shall set the fees for the following:

(a) Initial permit fee not to exceed $250.

(b) Biennial permit renewal not to exceed $250.

(c) Delinquent fee not to exceed $100.

(d) Change of location fee not to exceed $100.

History: Laws 1979, c. 79-226, § 1; Laws 1982, c. 82-225, § 36; Laws 1986, c. 86-256, § 16; Laws 1988, c. 88-172, § 6; Laws 1988, c. 88-205, § 14. Amended by Laws 1998, c. 98-200, § 127, eff. July 1, 1998; Laws 2009, c. 2009-223, § 27, eff. July 1, 2009; Laws 2011, c. 2011-141, § 14, eff. July 1, 2011.

NABP*LAW* 10/2013

Georgia

/GEORGIA/GEORGIA State Board of Pharmacy Regulations/GA BReg Chapter 480-15. Pharmacy Technicians and Other Pharmacy Personnel/GA BReg 480-15-.04. Duties of the Pharmacist in Charge Rclated to Registered Pharmacy Technicians.

GA BReg 480-15-.04.
Duties of the Pharmacist in Charge Related to Registered Pharmacy Technicians.

(a) The Pharmacist in Charge shall be responsible for:

(1) providing updated information to the Board in accordance with rules and regulations regarding the registered pharmacy technicians employed in the pharmacy for purposes maintaining the registry of registered pharmacy technicians established by the Board pursuant to paragraph (7) of subsection (a) of Code Section 26-4-28.

(2) Ensuring the reporting the separation of employment or termination of any Registered pharmacy technician for any suspected or confirmed criminal occupational-related activities committed or any drug-related reason, including but not limited to Adulteration, abuse, theft or diversion and shall include in the notice the reason for the termination.

(3) Assuring that all pharmacists and pharmacy interns and externs employed at the pharmacy are currently licensed and that registered pharmacy technicians employed at the pharmacy are currently registered with the Board of Pharmacy.

(4) Notifying the Board of any change in the employment status of all registered technicians in the pharmacy within 10 days of the technician's separation date from employment,

(5) Ensuring that registered pharmacy technicians in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and job title. The Pharmacist-in-Charge is responsible for ensuring that such persons wear or display such identification at all times when they are working in the prescription department.

(6) Shall ensure that the current registration for each registered pharmacy technician is readily accessible for inspection by the Board or Drugs and Narcotics Agents.

(7) Ensuring that a pharmacist is responsible for the dispensing of all prescription drug orders and for all activities of any pharmacy technician in the preparation of the drug for delivery to the patient, and that a pharmacist shall be present and personally supervising the activities of any pharmacy technician at all times.

(b) The Board of Pharmacy can take disciplinary action against the license of a pharmacist in charge who violates the provisions of this rule as authorized by O.C.G.A. Sections 43-1-19 and 26-4-60.

History: Adopted March 13, 2011.

NABP*LAW* 10/2013

Idaho

/IDAHO/IDAHO Board of Pharmacy Regulations/ID BReg Agency 27. Idaho State Board of Pharmacy/ID BReg Title 01./ID BReg Chapter 01. Rules of the Idaho State Board of Pharmacy/ID BReg Subchapter D. Profesional Practice Standards (Rules 300 through 599)/ID BReg 301. PIC Responsibilities.

ID BReg 301.
PIC Responsibilities.

The PIC is responsible for the management, and must maintain full and complete control, of every part of the pharmacy and its regulated operations. (3-21-12)

NABP*LAW* 09/2013

Illinois

/ILLINOIS/ILLINOIS Pharmacy Practice Regulations/IL BReg Title 68: Professions and Occupations/IL BReg Chapter VII. Department of Financial and Professional Regulation/IL BReg Part 1330. Pharmacy Practice Act/Subpart F. Pharmacy Standards./IL BReg Section 1330.660. Pharmacist-in-Charge.

IL BReg Section 1330.660.
Pharmacist-in-Charge.

a) No pharmacy shall be granted a license without a pharmacist being designated on the pharmacy license as pharmacist-in-charge.

b) A pharmacy shall have one pharmacist-in-charge who shall be routinely and actively involved in the operation of the pharmacy.

c) A pharmacist may be the pharmacist-in-charge for more than one pharmacy; however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge.

d) The responsibilities of the pharmacist-in-charge shall include:

1) Supervision of all activities of all employees as they relate to the practice of pharmacy;

2) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed (see Section 1330.600); and

3) Establishment and supervision of the record keeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.

e) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.

f) Within 30 days after a change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

g) In addition to notifying the Division within 30 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

1) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and

2) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.

h) The inventory described in subsection (g) of this Section shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion of the inventory and preservation of the inventory record, bearing the date of the inventory and the name and signatures of the departing and the incoming pharmacist-in-charge, shall be submitted to the Division at its principal office within 30 days after the change in the pharmacist-in-charge.

i) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (g), or that pharmacist-in-charge is incapacitated or deceased, the initial

inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to his or her initial inventory.

j) When the accuracy, relevance or completeness of any submitted documentation is questioned by the Division, because of a lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

1) Provide information as may be necessary; and/or

2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies or conflict of information.

k) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs shall be maintained for a period of 5 years either on site or at a central location where records are readily retrievable. Invoices shall be maintained on site for at least one year from the date of the invoice.

l) Whenever a pharmacy intends on changing or adding to the type of pharmacy services it offers, as listed in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540 and 1330.560, it shall notify the Division no less than 30 days prior to the change or addition.

NABP*LAW* 08/2013

Indiana

/INDIANA/INDIANA Board of Pharmacy Regulations/IN BReg Title 856. Indiana Board of Pharmacy/IN BReg Article 1. Pharmacies and Pharmacists/IN BReg 856 IAC Rule 28.1. Institutional Pharmacies and Pharmacy Services/IN BReg 856 IAC Rule 1-28.1-12. Drug distribution, storage, and accountability.

IN BReg 856 IAC Rule 1-28.1-12.
Drug distribution, storage, and accountability.

(a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge and the medical staff who explain the:

(1) selection;

(2) distribution;

(3) storage; and

(4) safe and effective use of:

(A) drugs;

(B) new drugs;

(C) investigational new drugs; and

(D) devices;

in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:

(1) The safe and efficient:

(A) distribution;

(B) control;

(C) storage; and

(D) accountability;

for all drugs and devices.

(2) The compliance with all applicable Indiana and federal laws and rules.

. . .

(f) Accountability requirements are as follows:

(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:

(A) controlled substances; and

(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.

(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:

(A) proofs-of-use documentation; or

(B) other electronic documentation methodology.

(3) At a minimum, the documentation process shall be able to identify the following:

(A) The name of the drug.

(B) The dose.

(C) The patient's name.

(D) The date and time of administration to the patient.

(E) The identification of the individual administering.

(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge for a period of not less than two (2) years.

History: (Indiana Board of Pharmacy; 856 IAC 1-28.1-12; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1641; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

NABP*LAW* 09/2013

Iowa

/IOWA/IOWA Board of Pharmacy Examiners Regulations/IA BReg Agency 657. Pharmacy Board/IA BReg Chapter 6. General Pharmacy Practice/IA BReg 657-6.2 (155A). Pharmacist in charge.

IA BReg 657-6.2 (155A).
Pharmacist in charge.

One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.

2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657--8.21(155A).

5. Ensuring that a pharmacist provides patient counseling as specified in rule 657--6.14(155A).

6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

7. Delivering drugs to the patient or the patient's agent.

8. Ensuring that patient medication records are maintained as specified in rule 657--6.13(155A).

9. Training pharmacy technicians and pharmacy support persons.

10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

11. Distributing and disposing of drugs from the pharmacy.

12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.

14. Establishing, implementing, and periodically reviewing and revising written policies and procedures to reflect changes in processes, organization, and other functions for all operations of the pharmacy and ensuring that all pharmacy personnel are familiar with those policies and procedures.

15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.

IA BReg 657-7.2 (155A).
Pharmacist in charge.

One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.

2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.

3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.

5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.

6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

7. Delivering drugs to the patient or the patient's agent.

8. Ensuring that patient medication records are maintained as specified in rule 657--7.10(124,155A).

9. Training pharmacy technicians and pharmacy support persons.

10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and pharmacy support persons.

11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

12. Distributing and disposing of drugs from the pharmacy.

13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.

15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

NABP*LAW* 10/2013

Kansas

/KANSAS/KANSAS State Board of Pharmacy Regulations/KS BReg Agency 68. Kansas State Board of Pharmacy/KS BReg Article 7. Miscellaneous Provisions/KS BReg 68-7-12. Responsibility of pharmacist-in-charge in other than a medical care facility pharmacy.

KS BReg 68-7-12.
Responsibility of pharmacist-in-charge in other than a medical care facility pharmacy.

Each pharmacist-in-charge for premises having a pharmacy registration, other than a medical care facility pharmacy, shall be responsible for the following functions.

(a) Each pharmacist-in-charge shall develop, supervise, and coordinate all pharmaceutical services carried on within the pharmacy to ensure compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations.

(b) Each pharmacist-in-charge shall be personally available to the extent required to ensure comprehensive pharmaceutical services within the pharmacy and to develop a staff of additional licensed pharmacists and supportive personnel as necessary to serve the needs of the pharmacy. Each pharmacist-in-charge shall maintain records in the pharmacy describing the training and education regarding work functions performed by all pharmacy personnel. Each pharmacist-in-charge shall maintain in the pharmacy written procedures that address the following areas:

(1) Designate the person or persons functioning as pharmacy technicians and supportive personnel;

(2) describe the functions of all personnel; and

(3) document the procedural steps taken by the pharmacist-in-charge to limit the functions of all personnel to their respective pharmacy work functions.

(c) Each pharmacist-in-charge shall develop or approve written policies and procedures for the pharmacy that meet all of the following conditions:

(1) Adequate accountability and control of drugs in compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations are provided for.

(2) Any incident that occurs as a result of an alleged or real error in filling or dispensing a prescription or medication order is brought to the attention of the pharmacist-in-charge and completely documented in accordance with the requirements of K.A.R. 68-7-12b.

(3) Adequate records of the pharmacy's dispensing, prepackaging, and bulk compounding actions are maintained, and all prepackaging of drugs is done in suitable containers, properly labeled in accordance with K.A.R. 68-7-16.

(d) Each pharmacist-in-charge shall develop written procedures for maintaining records of the pharmacy's dispensing, prepackaging, and bulk compounding actions and shall ensure that prepackaged medication is packaged in suitable containers and properly labeled.

(e) A pharmacist-in-charge who will no longer be performing the functions of the pharmacist-in-charge position shall inventory all controlled substances in the pharmacy before leaving the pharmacist-in-charge position. A record of the inventory shall be maintained for at least five years.

(f) Within 72 hours after beginning to function as a pharmacist-in-charge, the pharmacist-in-charge shall inventory all controlled substances in the pharmacy. A record of the inventory shall be maintained for at least five years.

History: (Authorized by K.S.A. 65-1630 and K.S.A. 2006 Supp. 65-1643; implementing K.S.A. 2006 Supp. 65-1626 and K.S.A. 2006 Supp. 65-1637; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1989; amended Nov. 30, 1992; amended Feb. 27, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003; amended July 20, 2007.)

NABP*LAW* 10/2013

Kentucky

/KENTUCKY/KENTUCKY Board of Pharmacy Regulations/KY BReg Title 201. Chapter 2. Board of Pharmacy/KY BReg 201 KAR 2:205. Pharmacist-in-Charge.

KY BReg 201 KAR 2:205.
Pharmacist-in-Charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities. (1) The pharmacist-in-charge shall be so designated in the application for a permit to operate a pharmacy and in each application for renewal of that permit thereafter.

(2) A pharmacist shall not serve as a pharmacist-in-charge:

(a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and

(b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.

(3) The pharmacist-in-charge shall be responsible for:

(a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;

(b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;

(c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;

(d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:

1. Employment of the pharmacist-in-charge;

2. Employment of staff pharmacists; or

3. Schedule of hours for the pharmacy;

(e) Making or filing of any reports required by state or federal laws and regulations;

(f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and

(g) Filing of any report of a theft or loss to:

1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);

2. The Department of the Kentucky State Police as required by KRS 315.335; and

3. The board by providing a copy to the board of each report submitted.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 07/2012;

(b) "Application for Non-Resident Pharmacy Permit", Form 1, 07/2012;

(c) "Application for Resident Pharmacy Renewal", Form 2, 07/2012; and

(d) "Application for Non-Resident Pharmacy Permit Renewal", Form 2, 07/2012.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

History: Adopted effective November 30, 1992; Amended effective September 11, 2000; Amended effective February 1, 2013.

NABP*LAW* 09/2013

Louisiana

/LOUISIANA/LOUISIANA Board of Pharmacy Regulations /LA BReg Title 46: Professional and Occupational Standards/LA BReg Part LIII: Pharmacists/LA BReg Chapter 11. Pharmacies/LA BReg Subchapter A. General Requirements/LA BReg 1105. Pharmacist-in-Charge.

LA BReg 1105.
Pharmacist-in-Charge.

A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.

1. The acquisition of the PIC privilege shall require:

a. possession of an active Louisiana pharmacist license;

b. active pharmacy practice for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and

c. the completion of the affidavit of responsibility and duties described below.

2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.

C. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.

E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.

F. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.

G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.

H. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.

I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within 10 days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge.

2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within 10 days of the departure of the prior pharmacist-in-charge.

3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least 10 days prior to this voluntary departure, unless replaced in a shorter period of time.

J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.

K. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless approved by the board.
History: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, LR 38:1239 (May 2012).

NABP*LAW* 09/2013

/LOUISIANA/LOUISIANA Board of Pharmacy Regulations /LA BReg Title 46: Professional and Occupational Standards/LA BReg Part LIII: Pharmacists/LA BReg Chapter 27. Controlled Dangerous Substances/LA BReg Subchapter F. Production, Distribution, and Utilization/LA BReg 2747. Dispensing Requirements.

LA BReg 2747.
Dispensing Requirements.

A. Location of Dispensing Activities. A pharmacist may dispense a prescription for a controlled substance pursuant to a valid prescription or order while in the usual course of his professional practice, but only within a prescription department in a pharmacy licensed by the board. A valid prescription or order is a prescription or order issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.

. . .

E. Professional Conduct. A license, registration, certification, permit, or any other credential deemed necessary to practice, or assist in the practice of, pharmacy may be subject to discipline when deviating from primary or corresponding responsibility to avert the following prohibited acts.

1. Primary responsibility:

a. drug diversion--attempted, actual or conspired dispensing , distributing, administering, or manufacturing of a controlled substance not pursuant to a valid prescription or order while acting in the course of professional pharmacy practice is prohibited; or

b. possession--actual or conspired possession of a controlled substance not pursuant to a valid prescription or order issued for a legitimate medical purpose by an authorized practitioner in the usual course of professional practice.

2. Corresponding Responsibility

a. Medical Purpose. The prescribing practitioner has the primary responsibility to issue a prescription for a controlled substance for a legitimate medical purpose, but a corresponding responsibility rests with the pharmacist or dispensing physician dispensing said prescription to ascertain that said prescription was issued for a legitimate medical purpose in the usual course of professional practice.

b. Authenticity. A pharmacist or dispensing physician shall exercise sound professional judgment to ascertain the validity of prescriptions for controlled substances. If, in the pharmacist's professional judgment, a prescription is not valid, said prescription shall not be dispensed.

3. Forged Prescriptions. It is unlawful to forge a prescription, or to dispense a forged prescription, for a controlled substance. The pharmacist or dispensing physician shall exercise professional diligence in determining the validity of a prescription as to the practitioner's authority and/or patient's identity, in order to prevent misrepresentation, fraud, deception, subterfuge, conspiracy, or diversion of controlled substances.

4. Altered Prescriptions. It is unlawful to personally alter a prescription, or to dispense an altered prescription, for a controlled substance, except as provided by §2747.B.4 of this Chapter.

F. Accountability. The pharmacist-in-charge, the owner of a pharmacy permit, and/or other designated responsible parties, shall be accountable for shortages of controlled substances or inconsistencies indicated in an audit.

History: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008).

NABP*LAW* 09/2013

Maine

/MAINE/MAINE Board of Pharmacy Regulations/ME BReg 02. Department of Professional and Financial Regulation/ME BReg 392. Board of Pharmacy/ME BReg Part 2.

ME BReg 3.
Administrative Responsibilities.

1. Verification of Registration

The pharmacist in charge shall ensure that each pharmacy technician employed at the drug outlet for which the pharmacist in charge is responsible is registered with the board. A pharmacy technician shall carry the wallet-sized registration card issued by the board at all times the technician is on duty and shall produce the card upon request of the pharmacist in charge, a pharmacist on duty or an inspector of the board. No pharmacist in charge or pharmacist on duty shall permit a person who is not registered pursuant to the terms of this chapter to perform the duties of a pharmacy technician.

2. Display of Registration Certificate

The pharmacist in charge shall prominently display for public view the registration certificates of all pharmacy technicians employed at the drug outlet for which the pharmacist in charge is responsible. If the pharmacy technician works at multiple sites, the certificate shall be displayed at the technician's primary work site.

3. Notice of Employment and Non-Employment of Pharmacy Technicians

The pharmacist in charge shall notify the board via letter, fax or email within 14 days after the commencement or cessation of employment of any pharmacy technician at a retail drug outlet for which the pharmacist in charge is responsible:

4. Notice of Termination of Employment for Drug-Related Reason

The pharmacist in charge shall notify the board via letter, fax or email of the termination of employment of a pharmacy technician for any drug-related reason, including but not limited to adulteration, abuse, theft and diversion, and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination.

NABP*LAW* 10/2013

<u>Mississippi</u>

/MISSISSIPPI/MISSISSIPPI State Board of Pharmacy Regulations/Title 30. Professions and Occupations/MS BReg Subtitle 20. Board of Pharmacy/Part 3001. Board Regulations/MS BReg 30-20-3001:VII. Responsibility of Pharmacist-In-Charge (PIC).

MS BReg 30-20-3001:VII.
Responsibility of Pharmacist-In-Charge (PIC).

1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.

A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and, that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted.

A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full time basis.

B. Recommended Guidelines:

(1) That each individual work space is designed to provide space and a work flow design that will accommodate the workload in an organized fashion; and

(2) That the computer's software should be of a design so that drug interactions and contraindications must be reviewed by the pharmacist. Further, the computer system should support counseling and drug utilization review documentation; and

(3) That trained supportive staff should be maintained to meet the demands of the practice site, workload and the clientele served; and

(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

(5) That all staff should be afforded and encouraged to participate in training and continuing education in order to keep them abreast of new information and changes in the field; and

(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.

C. Circumvention. It is a violation of this section for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department for the compliance with federal and state drug or pharmacy laws and regulations. Any such circumvention may result in charges being filed against the pharmacy permit.

2. A permit for a pharmacy located within the state shall not be issued or renewed unless such person be a pharmacist licensed in this state.
If the pharmacist license of the pharmacist-in-charge becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, application must be made for a new pharmacy permit by another pharmacist within ten (10) days.

3. If the employment of a pharmacist-in-charge is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the PIC, he/she must:

A. Return the permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the pharmacist-in-charge for that facility and;

B. In accordance with the provision of paragraph 2 of ARTICLE XXV of the Regulations, send to the Board of Pharmacy an inventory of any controlled substances on hand at the facility at the time of his/her termination as pharmacist-in-charge.

C. When the relinquishing PIC cannot or does not comply with the inventory requirements of this paragraph it shall be the responsibility of the new PIC to send to the Board of Pharmacy an inventory of any controlled substances on hand at the time he/she assumes responsibility as PIC.

D. The relinquishing PIC is responsible for notification of appropriate supervisors or owners of the surrender of the permit.
When a permit is thus returned for a facility, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

4. If a permitted facility is permanently closed or has a change of ownership, the pharmacist-in-charge for that facility shall give notice to the Board of the effective date of closure or change in ownership and include the storage location of the businesses records and appropriate contact information. If a permitted facility has a change in name or location, application for a new permit must be made to the Board at least ten (10) days prior to the change in name or location. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. On the premises where a pharmacy is maintained in conjunction with other services or business activities, the pharmacy shall be physically secured from such other services or activities during those times a pharmacist is not present and the pharmacy is not open and other services or activities are being provided on the premises.

A. The Pharmacy shall be secured by a physical barrier to detect entry at a time when the Pharmacist is not present.

B. Each pharmacist while on duty shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.

C. The pharmacist-in-charge shall be responsible for adequate security being maintained on drugs in all areas of the permitted facility at all times and is responsible for reporting any loss or suspected loss of controlled substances or legend drugs directly to the Board immediately (this

does not relieve any pharmacist who discovers a loss from the requirement of reporting the loss directly to the Board).

6. Each facility issued a pharmacy permit by the Mississippi Board of Pharmacy shall maintain:

A. An area of sufficient size to accommodate the dispensing functions of the facility and which is adequately equipped to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their dispensing as stipulated by the USP-NF and/or the Manufacturer's or Distributor's labeling.

B. A sink with hot and cold running water which is convenient to the dispensing area;

C. An inventory which shall include such drugs, chemicals and preparations as may be necessary to fill ordinary prescriptions as indicated by experience in the area where the pharmacy is located;

D. Technical equipment which may include measuring graduates, mortar and pestle, spatulas, funnels, ointment slab or paper, balance and such other items of equipment found to be necessary for the filling of prescriptions or rendering of other pharmacist services; and,

E. Current reference material adequate for professional and consumer information.

F. Pharmacy permits, facility controlled substance registrations, and DEA registrations must be conspicuously posted. Evidence of current pharmacist licensure and pharmacy technician registration must be provided on request by any agent of the Board.

G. A current and updated copy of the Mississippi Board of Pharmacy Practice Regulations and Pharmacy Practice Act.

7. It is the responsibility of the Pharmacist-in-charge to establish and implement procedures to ensure compliance with the Article entitled Prescription Monitoring Program.

8. The pharmacist-in-charge shall be responsible for written policies and procedures for maintaining the integrity and confidentiality of prescription and patient health care information. All employees of the pharmacy with access to any such information shall be required to read, sign, and comply with the established policies and procedures.

History: Amended Jan. 31, 2011; June 3, 2012; Jan. 1, 2013; April 26, 2013.

NABP*LAW* 10/2013

Missouri

/MISSOURI/MISSOURI Board of Pharmacy Regulations/MO BReg Title 20. Dept. of Insurance, Financial Institutions and Professional Registration/MO BReg Div. 2220. Chapter 2. General Rules/MO BReg 20 CSR 2220-2.090. Pharmacist-in-Charge.

MO BReg 20 CSR 2220-2.090.
Pharmacist-in-Charge.

Purpose: This rule defines the term pharmacist-in-charge, sets the requirements and standards for this title, and defines the term full-time pharmacy.

(1) A pharmacist may be a pharmacist-in-charge of a licensed pharmacy; provided, that s/he complies with all provisions of this rule.

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

(A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;

(B) The traffic in the prescription area must be restricted to authorized personnel only so that proper control over the drugs can be maintained at all times;

(C) All the required signs are displayed in the appropriate places when there is no pharmacist on duty;

(D) The licenses of all pharmacists employed are conspicuously displayed in the pharmacy;

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

(F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;

(G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;

(H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;

(I) The Missouri Revised Negative Drug Formulary and state laws governing drug substitution be complied with when generic substitution takes place;

(J) If exempt narcotics are sold, complete records be kept of all exempt narcotics in a bound exempt narcotic register;

(K) If poisons are sold, the pharmacy maintain a poison register;

(L) The pharmacy maintain and have on file at all times the required reference library;

(M) The pharmacy be kept in a clean and sanitary condition;

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

(O) All Missouri and federal licenses are kept up-to-date;

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

(Q) All equipment, as prescribed through regulation, is available and in good working order;

(R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;

(S) Any changes of the following are appropriately carried out:

1. Pharmacy permit transfer of any type or manner;

2. Regulation requirements completed satisfactorily when a change of pharmacist-in-charge occurs;

3. Change of pharmacist's own address as it appears on his/her license;

(T) When the board-recognized pharmacist-in-charge is changed at that licensed facility, an appropriate documented inventory of controlled substances must be taken;

(U) Assure that the appropriate handling and disposal of controlled substances is done and verified through appropriate documentation and when necessary that controlled substances be disposed of through appropriate procedures involving the Missouri Board of Pharmacy or the Bureau of Narcotics and Dangerous Drugs;

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

(X) Compliance with state and federal requirements concerning drug samples;

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded;

(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed drug distributions are exceeded;

(AA) Assure overall compliance with state and federal patient counseling requirements;

(BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list;

(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;

(DD) Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy shall be required to register with the board as a pharmacy technician. The determination of whether or not an individual must register as a pharmacy technician will be the responsibility of the pharmacist-in-charge; and

(EE) Maintain compliance of automated dispensing and storage systems with applicable board rules and regulations.

History: sections 338.140, 338.240 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.090. Emergency rule filed April 12, 1984, effective April 22, 1984, expired Aug. 20, 1984. Original rule filed April 12, 1984, effective Aug. 11, 1984. Amended: Filed Feb. 25, 1986, effective Aug. 11, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Dec. 30, 1998, effective June 30, 1999. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.090, effective Aug. 28, 2006.

NABP*LAW* 09/2013

Montana

/MONTANA/MONTANA Board of Pharmacy Regulations /MT BReg Title 24. Department of Labor and Industry/MT BReg Chapter 174. Board of Pharmacy/MT BReg Subchapter 11. Institutional Pharmacies/MT BReg 24.174.1104. Institutional pharmacist and pharmacist-in-charge responsibility.

MT BReg 24.174.1104.
Institutional pharmacist and pharmacist-in-charge responsibility.

(1) The pharmacy director/pharmacist-in-charge shall provide for applicable policies and procedures to ensure:

(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing will provide education and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) a policy by which an offer is made to convey the discharge medication regimen to a patient's pharmacies;

(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) pharmacy participation in formulary development;

(h) participation in drug utilization review and monitoring of adverse drug reactions and development of procedures to avoid problems identified;

(i) evaluation of reported medication errors and development of procedures to prevent those errors;

(j) proper acquisition and secure, temperature-controlled storage of all prescription drugs;

(k) quality control of sterile and nonsterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) pharmacy safety and security;

(m) utilization of registered technicians or technicians in training;

(n) accurate distribution systems and secure, temperature-controlled storage of pharmaceutical products throughout the institution;

(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) the appropriate use, security and accountability of controlled substances;

(q) staff development and competency evaluation;

(r) maintenance of all required records; and

(s) compliance with all other requirements of the Montana Board of Pharmacy.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-307, 37-7-308, MCA; NEW, 2002 MAR p. 3605, Eff. 12/27/02.

NABP*LAW* 10/2013

New Hampshire

/ NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 700. Standards of Practice/NH BReg Part Ph 704. Dispensing of Drugs and Devices/NH BReg Ph 704.11. Pharmacist-in-Charge Requirements/Duties.

NH BReg Ph 704.11.
Pharmacist-in-Charge Requirements/Duties.

(a) The pharmacist-in-charge or the pharmacist on duty shall control all aspects of the practice of pharmacy.

(b) The pharmacist-in-charge shall be responsible for the control of all drugs issued or dispensed in the pharmacy where he/she practices as well as:

(1) Establishing written policies and procedures for the procurement, storage, compounding, and dispensing of drugs;

(2) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;

(3) Supervising personnel in the prescription department;

(4) Establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, and repackaging of drugs;

(5) Maintaining the security of the prescription department and its contents;

(6) Determining who will have keys and access to the pharmacy;

(7) Ensuring the medication dispensed is in conformance with the prescription received;

(8) Prohibiting the presence of misbranded drugs in the pharmacy; and

(9) Ensuring compliance with the provisions of RSA 318 and RSA 318-B and any other state or federal pharmacy-related laws or rules.

(c) A pharmacist may serve as a pharmacist-in-charge for a maximum of 2 pharmacies, providing that one of these pharmacies shall be in an institution requiring the services of a pharmacist only on a part-time basis.

NABP*LAW* 08/2013

NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 700. Standards of Practice/NH BReg Part Ph 709. Institutional Practices/NH BReg Ph 709.04. Drug Security.

NH BReg Ph 709.04.
Drug Security.

(a) Drugs stored in any area or department of the facility shall be plainly labeled and kept in a specifically designated, well-illuminated cabinet, closet or storage area and shall be accessible only to
authorized personnel.

(b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used.

(c) When using an automated medication supply system, the pharmacist-in-charge or designee shall have the responsibility for developing a secure system to assign, discontinue or change personnel access codes.

(d) A pharmacist or registered pharmacy technician under the direction of a pharmacist shall visit and create a retrievable record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A retrievable record of each monthly inspection specified in (d) above shall be maintained in the pharmacy for at least 2 years and shall be available to the board upon request.

(f) The pharmacist-in-charge shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs.

(h) Discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. Missing or unaccounted controlled drugs shall be reported to the NH board and Drug Enforcement Agency (DEA) as specified by 21 CFRx1301.76-b.

(i) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

NABP*LAW* 08/2013

/NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 800. Pharmacy Technicians/NH BReg Part Ph 805. Revocatiou and Denilal/NH BReg Ph 805.01. Effect of Revocation and Denial.

NH BReg Ph 805.01.
Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or, after notice and hearing, shall revoke a registration whenever the board finds by the preponderance of the evidence any of the following:

(1) That the applicant does not possess good moral character;

(2) That the applicant, or registrant, has willfully violated any of the provisions of RSA 318; RSA 318-B and/or the board's Code of Administrative Rules;

(3) That the applicant has been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation;

(4) That the applicant has attempted to obtain a pharmacy technician registration by fraudulent means;

(5) That the applicant is unable to engage in the performance of pharmacy technician functions with reasonable skill and safety by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals or any other substance, or as a result of any mental or physical condition;

(6) The suspension, revocation, or probation by another state of the applicant's license, permit, or registration to practice as a pharmacy technician;

(7) That the applicant refused to appear before the board after having been ordered to do so in writing; or

(8) That the applicant made any fraudulent or untrue statement to the board.

(b) The pharmacist-in-charge shall notify the board, in writing, within 7 calendar days after becoming aware that a pharmacy technician has adulterated, abused, stolen or diverted drugs.

NABP*LAW* 08/2013

New Jersey

NEW JERSEY/NEW JERSEY State Board of Pharmacy Regulations/NJ BReg Title 13. Law and Public Safety/NJ BReg Chapter 39. State Board of Pharmacy/NJ BReg Subchapter 4. Pharmacy Permit Requirements/NJ BReg 13:39-4.15. Security of pharmacies and pharmacy departments.

NJ BReg 13:39-4.15.
Security of pharmacies and pharmacy departments.

(a) The pharmacist(s) on duty in all pharmacies, including pharmacy departments, shall be responsible for:

1. Keeping the pharmacy or pharmacy department closed and the security system turned on at all times when he or she is not present within the permitted premises in the case of a pharmacy, or, in the case of a pharmacy department, when he or she is not present within the department, except as provided in N.J.A.C. 13:39-6.4;

i. In the case of a pharmacy or pharmacy department that has been issued an institutional permit, pharmacy technicians may remain within the permitted premises when the pharmacy or pharmacy department is closed and secured, if the pharmacist determines, based on his or her professional judgment, that the security of prescription legend drugs, devices and controlled substances will be maintained in the pharmacist's absence;

2. Ensuring that the security of the prescription dispensing area and its contents are maintained at all times, including the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription dispensing area; and

3. Reporting all thefts or diversions of prescription legend drugs and devices and controlled substances, and any significant loss of prescription legend drugs and devices and controlled substances, to the pharmacist-in-charge or the pharmacy permit holder upon discovery. When determining whether a loss of prescription legend drugs or devices or controlled substances is significant, the following factors shall be considered, consistent with 21 CFR 1301.74(c):

i. The actual quantity of prescription legend drugs, devices or controlled substances missing in relation to the type of business;

ii. The specific prescription legend drug, device or controlled substance missing;

iii. Whether the loss of the prescription legend drug, device or controlled substance can be associated with access to those drugs, devices or controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drugs, devices or controlled substances;

iv. A pattern of losses over a specific time period, whether the losses appear to be random and the results of efforts taken to resolve the losses;

v. If known, whether the specific prescription legend drugs, devices or controlled substances are likely candidates for theft or diversion; and

vi. Local trends and other indicators of the theft or diversion potential of the missing prescription legend drug, device or controlled substance.

(b) The holder of a pharmacy or pharmacy department permit and the pharmacist-in-charge of the pharmacy or pharmacy department shall ensure that:

1. All entrances to the pharmacy or pharmacy department are capable of being locked and are connected to a monitored security system that transmits an audible, visual or electronic signal warning of intrusion. The security system shall be equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or is disabled. Only the pharmacist-in-charge shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department;

2. If a theft or diversion of prescription legend drugs or devices or controlled substances, or a significant loss of prescription legend drugs or devices or controlled substances, as delineated in (a) above, is reported to the pharmacist-in-charge, the pharmacist-in-charge shall notify the holder of the pharmacy or pharmacy department permit of such report. The pharmacist-in-charge and the holder of the pharmacy or pharmacy department permit shall ensure that:

i. A written report is filed with the Board upon discovery of the theft or diversion or the significant loss of prescription legend drugs or devices; and

ii. A written report is filed with the Federal Drug Enforcement Administration upon discovery of the theft or diversion or any significant loss of controlled substances, consistent with Federal requirements. A copy of such report shall be filed with the Office of Drug Control, consistent with State requirements and with the Board;

3. There is a secure area for receiving packages known to contain prescription legend drugs and devices and controlled substances. No prescription drug shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided; and

4. If a drop-off device is utilized for prescriptions, it is of a one-way, irretrievable and secure design.

(c) In addition to the requirements set forth in (b) above, the holder of a pharmacy department permit and the pharmacist-in-charge of the pharmacy department shall also ensure that:

1. The pharmacy department is constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto;

2. All medications requiring supervision of a pharmacist, including dispensed medication, remain within the confines of the department when the pharmacist is not in the pharmacy department;

3. The pharmacy department has a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department; and

4. The telephone number of the pharmacist-in-charge is available in the office of the manager of the establishment.

(d) The holder of a pharmacy or pharmacy department permit shall comply with any law and/or ordinance of the municipality in which the pharmacy or pharmacy department is located requiring the placement of a security key box on the exterior of the pharmacy or the premises in which the pharmacy department is located for purposes of permitting emergency access to the premises.

History: Amended by R.1994 d.351, effective July 18, 1994; R.1999 d.214, effective July 19, 1999. Recodified from N.J.A.C. 13:39-4.15 and amended by R.2005 d.25, effective January 18, 2005. Adopted by R.2009 d.247, effective August 3, 2009. Recodified from N.J.A.C. 13:39-4.14 and amended by R.2010 d.90, effective June 21, 2010.

NABP*LAW* 10/2013

/NEW JERSEY/NEW JERSEY State Board of Pharmacy Regulations/NJ BReg Title 13. Law and Public Safety/NJ BReg Chapter 39. State Board of Pharmacy/NJ BReg Subchapter 9. Pharmaceutical Services for Health Care Facilities/NJ BReg 13:39-9.23. Storage and security.

NJ BReg 13:39-9.23.
Storage and security.

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall be responsible for all the medications in the facility.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the drug manufacturer.

(b) The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, proper storage, misbranding, physical integrity, security and accountability of all drugs. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by the pharmacy technician, intern or extern and co-signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the health care facility.

(c) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

History: Recodified from 13:39-9.16 by R.1994 d.351, effective July 18, 1994; R.1999 d.214, effective July 19, 1999. Recodified from N.J.A.C. 13:39-9.25 and amended by R.2005 d.25, effective January 18, 2005. Amended by R.2010 d.90, effective June 21, 2010.

NABP*LAW* 10/2013

NJ BReg 13:39-11.12.
Pharmacist-in-charge responsibilities

(a) The pharmacist-in-charge shall supervise all sterile compounding performed by pharmacy personnel. The pharmacist-in-charge shall be trained in aseptic manipulation skills.

(b) The pharmacist-in-charge shall be responsible for, at a minimum, the following:

1. Determining the procedural, environmental, and quality control practices that are necessary for the risk levels he or she assigns to specific compounded sterile preparations;

2. Ensuring that the selected sterilization method both sterilizes and maintains the strength, purity, quality, and packaging integrity of the compounded sterile preparations;

3. Ensuring the placement in buffer areas and ante areas of equipment (for example, refrigerators), devices (for example, computers and printers) and objects (for example, carts and cabinets) that are not essential to compounding is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring;

4. Storage of all materials pertinent to the compounding of sterile preparations, including drugs, chemicals, and biologicals, and the establishment of specific procedures for procurement of the materials in accordance with State and Federal laws and regulations;

5. Ensuring that all packaging and labeling of all compounded sterile preparations in the pharmacy are performed under the immediate personal supervision of a pharmacist;

6. Ensuring that preparation and compounding of sterile preparations is performed only by pharmacists who have been trained in aseptic manipulation skills, or by pharmacy technicians, pharmacy interns, or pharmacy externs who have been trained in aseptic manipulation skills working under the immediate personal supervision of a pharmacist trained in aseptic manipulation skills;

7. Recording all transactions of the pharmacy as may be necessary under applicable State, Federal, and local laws and rules, to maintain accurate control over, and accountability for, all pharmaceutical materials, and ensuring that policies and procedures exist with respect to the maintenance of the audit trail required pursuant to N.J.A.C. 13:39-11.20;

8. Ensuring that all pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs who compound sterile preparations are trained and evaluated consistent with the requirements of N.J.A.C. 13:39-11.16;

9. Establishing procedures for maintaining the integrity of the product and the manufacturer's control identity when repackaging sterile products. A pharmacist shall check all repackaging and shall initial the repackaging records;

10. Disposal of all unused drugs and materials used in compounding sterile preparations, including antineoplastic agents and other hazardous substances, in accordance with accepted professional standards, and the Medical Waste Act, N.J.S.A. 13:1E-48.1 et seq., so as not to endanger the public health;

11. Ensuring that the compounding area and its contents and other areas where compounded sterile preparations are present are secured, so as to prevent access by unauthorized personnel;

12. Ensuring that the pharmacy contains, in addition to the minimum reference library mandated in N.J.A.C. 13:39-5.8(a) 1, references pertinent to compounding sterile preparations;

13. Ensuring that records are maintained that document, at least once daily, that appropriate controlled cold (refrigerator), controlled freezer, if applicable, and controlled room temperatures, as these terms are defined in United States Pharmacopeia 797, are maintained. Such records shall be maintained for no less than five years and shall be made available to the Board for inspection upon request;

14. Ensuring that all information required to be maintained as part of a pharmacy's patient profile record system pursuant to N.J.A.C. 13:39-7.19 or 9.19 is maintained for all compounded sterile preparations;

15. Ensuring that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available; and

16. Maintaining a policy and procedures manual detailing the pharmacy's standard operating procedures with regard to compounded sterile preparations, consistent with the requirements of N.J.A.C. 13:39-11.23, and maintaining a written quality assurance program, consistent with the requirements of N.J.A.C. 13:39-11.24.

History: Adopted by R.1998 d.297, effective June 15, 1998. Recodified from N.J.A.C. 13:39-11.6 and amended by R.2005 d.25, effective January 18, 2005. Recodified from N.J.A.C. 13:39-11.5 and amended by R.2013 d.084, effective June 3, 2013.

NABP*LAW* 10/2013

Oklahoma

/OKLAHOMA/OKLAHOMA State Board of Pharmacy Regulations/OK BReg Title 535. Oklahoma State Board of Pharmacy/OK BReg Chapter 15. Pharmacies/OK BReg Subchapter 3. Pharmacies/OK BReg 535:15-3-2. Pharmacy responsibilities.

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.

(b) Pharmacy manager. Each pharmacy, in order to obtain and maintain a pharmacy license, must have a registered pharmacist as the pharmacy manager.

(1) A pharmacy manager (i.e. pharmacist in charge) is designated by his signature on the original pharmacy application or by the appropriate notification to the Board as required in 535:15-3-10(a), and is responsible for all aspects of the operation related to the practice of pharmacy. These responsibilities include, but are not limited to the:

(A) supervision of all employees as they relate to the practice of pharmacy;

(B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;

(C) proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;

(D) proper display of all licenses;

(E) annual controlled drug inventory; and,

(F) maintenance of prescription files;

(2) Failure of the pharmacy to have a pharmacy manager who fulfills these responsibilities is a violation of this code by both the pharmacy and pharmacy manager (PIC).

(3) No pharmacist may serve as a pharmacy manager in more than one pharmacy at a time.

(4) A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager.

(c) Pharmacy manager's and pharmacy's responsibilities. The following describe responsibilities of the pharmacy and pharmacy manager.

(1) Where the actual identity of the filler of a prescription is not determinable, the manager of the pharmacy and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board of Pharmacy.

(2) The pharmacy and the pharmacy manager are responsible to establish and maintain effective controls against prescription errors or misfills.

(3) The pharmacy and/or pharmacy manager shall notify the Board immediately by certified mail of the separation of employment of any pharmacist, pharmacy intern, or pharmacy technician for any suspected or confirmed drug or pharmacy related violation. If the pharmacy manager (PIC) is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board by certified mail.

(4) Establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(5) The pharmacy, pharmacist and pharmacy manager are responsible for supervision of all employees as they relate to the practice of pharmacy.

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History: Amended at 12 Ok Reg 2593, eff 6-26-95; Amended at 14 Ok Reg 3024, eff 7-1-97; Amended at 15 Ok Reg 3272, eff 7-13-98; Amended at 17 Ok Reg 2626, eff 7-1-00; Amended at 18 Ok Reg 2736, eff 7-1-01; Amended at 20 Ok Reg 2476, eff 7-11-03; Amended at 21 Ok Reg 2452, eff 7-1-04; Amended at 24 Ok Reg 2257, eff 7-1-07; Amended at 27 Ok Reg 2249, eff 7-11-10

NABP*LAW* 10/2013

/OKLAHOMA/OKLAHOMA State Board of Pharmacy Regulations/OK BReg Title 535. Oklahoma State Board of Pharmacy/OK BReg Chapter 15. Pharmacies/OK BReg Subchapter 6. Hospital Drug Room Rules/OK BReg 535:15-6-5. Drug room and PIC responsibilities and duties.

OK BReg 535:15-6-5.
Drug room and PIC responsibilities and duties.

(a) Responsibilities. Responsibilities of the hospital drug room and PIC include drug purchasing, acquisition, preparation, distribution, monitoring, security, storage and control.

(1) Written procedures. The hospital drug room and PIC shall establish written procedures for the safe and efficient acquisition, distribution, and utilization of all medicine products with any of the Federal legends such as "RX only" and medications administered or distributed in the hospital system. A current copy of such procedures shall be available for review by the Board.

(2) General Responsibility. The hospital drug room and PIC shall be responsible for the safe and efficient monitoring, distribution, control, purchasing, acquisition and accountability of all drugs including but not limited to Federal legend drug products used in diagnostic procedures, I.V. fluids, or contained in supply kits excluding blood bank products and reagents controlled by the

laboratory. The other professional staff of the hospital facility shall cooperate with the pharmacist in meeting this responsibility.

(3) Confidentiality. The hospital drug room and PIC shall have responsibility for establishing policies for the security and integrity of any patient information, confidential and non-confidential, and must abide by all relevant State and Federal regulations applicable to the hospital system.

(4) Adverse Drug Events Program. The hospital drug room and PIC shall develop and maintain a program to monitor the actual and potential adverse drug events including pharmacist interventions, medication errors, and adverse drug reactions for all medications utilized in the hospital to include system wide programs if an integrated system is involved. Records indicating the tracking, review, and outcome of the Adverse Drug Events shall be kept current and available for Board inspection.

(5) Investigational drug programs. The PIC shall establish a policy for investigational drug use.
(6) Review of medication orders. The PIC shall cause medication orders to be reviewed by a pharmacist in a timely manner.

(7) Pharmacists Visits. The hospital drug room and PIC shall cause and document a minimum of 52 routine in-house visits per year to be made to a hospital with a drug room as required by health department rule OAC 310:667-21-2(a) et seq.

(A) No more than 2 visits in any 7-day period shall be counted towards this minimum.

(B) Visits in any calendar month shall be no less than 2.

(C) The PIC shall submit a report outlining issues encountered and decisions made during visits. A copy of this report shall be available in the hospital drug room for inspection by the Board.

(D) A licensed hospital drug room employing a full-time pharmacist is not required to document the 52 routine in-house visits since daily work is done, interventions are documented, and audit systems are maintained.

(8) Pharmacy and Therapeutics (P&T) Committee. The PIC shall be a participating member in the Pharmacy and Therapeutics Committee.

(9) Effective Controls. The hospital drug room and PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(b) Duties. The duties of a PIC in a licensed hospital drug room, at a minimum, shall be the following:

(1) The training duties of the PIC are:

(A) Competency training regarding preparation and sterilization of parenteral medications prepared by appropriate hospital staff;

(B) Competency training of personnel concerning medicine incompatibilities and providing incompatibility information; and

(C) Training personnel in confidentiality of protected health and proprietary information and regarding the compliance with all federal and state laws and regulations applicable to the hospital drug room.

(i) Such rules regarding confidentiality of patient records are described in 535:15-3-14(e), the federal HIPAA regulations; and,

(ii) Such responsibilities for confidentiality shall be as set forth in 535:10-3-1.1 (a) (6) and 535:10-3-1.2 (a) (14) and the rules of this Title.

(D) Conducting initial and continuing competency training of all drug room personnel.

(2) Repackaging drug products including unit dose.

(3) Establishing procedures for procurement of all medicines used within the hospital system subject to approval of the medical and professional staff.

(4) Participating in the development and maintenance of a formulary for use within the hospital system.

(5) Maintaining and making available a sufficient inventory of medicines including antidotes and other emergency drugs approved by the medical and professional staff, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

(6) Maintaining oversight of the records of all transactions of the drug room required by applicable local, state, and federal law, and necessary to maintain accurate control and accountability for all medications.

(7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to medicine utilization and effectiveness.

(8) Cooperating fully with teaching and/or research programs in the hospital facility, if any.

(9) Implementing the policies and decisions of the appropriate committees of the medical and professional staff that deal with drug distribution.

(10) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations governing the practice of pharmacy within a hospital facility.

(11) Establishing guidelines for the safe and effective distribution of medicines intended for floor stock, and their subsequent administration.

History: Added at 20 Ok Reg 2479, eff 1-1-04; Amended at 27 Ok Reg 2249, eff 7-11-10]

NABP*LAW* 10/2013

/OKLAHOMA/OKLAHOMA State Board of Pharmacy Regulations/OK BReg Title 535. Oklahoma State Board of Pharmacy/OK BReg Chapter 15. Pharmacies/OK BReg Subchapter 6. Hospital Drug Room Rules/OK BReg 535:15-6-7. Drug distribution and control.

OK BReg 535:15-6-7.
Drug distribution and control.

(a) General. The PIC shall establish written procedures for the safe and efficient distribution of medicine products. A copy of such procedures shall be on hand for inspection by the Board.

(b) Responsibility. The PIC shall be responsible for the safe and efficient distribution, control, and accountability of drugs. The other professional staff of the hospital facility shall cooperate with the PIC in meeting this responsibility. The PIC shall be responsible for, at a minimum, the following:

(1) Competency education and training of nursing personnel concerning admixture of parenteral products, and incompatibility and provision of proper incompatibility information.

(2) Prepackaging and/or preparing of drug products including certification of unit dose.

(3) Establishing of specifications for procurement of all materials, including drugs, chemicals, and biologicals used within the hospital system, subject to approval of the appropriate committee of the hospital system.

(4) Participating in the development and maintenance of a formulary for use within the hospital facility.

(5) Maintaining and making available a sufficient inventory of medicines, including antidotes and other emergency drugs, for use within the hospital facility. In addition, current references, antidote information, and telephone numbers of regional reference centers such as Poison Centers and Drug Information Centers shall be maintained and readily available throughout the hospital.

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(6) Reviewing records of all transactions of the hospital drug room required by applicable local, state, and federal law, necessary to maintain accurate control and accountability for all medicine materials.

(7) Participating in those aspects of the hospital facility's patient care evaluation programs that relate to drug utilization and effectiveness.

(8) Developing a mechanism to implement the policies and decisions of the appropriate committees of the hospital that deal with drug distribution and drug utilization.

(9) Meeting all inspection and other requirements of the Oklahoma Pharmacy Act, and those rules and regulations applying to hospital drug rooms.

(10) Establishing floor stock guidelines for the safe and effective distribution of drugs intended for floor stock, and their subsequent administration.

(11) Fully cooperating with teaching and/or research programs in the hospital facility, if any.

(12) Prepackaging medications included in the hospital drug room formulary in 535:15-6-9.

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History: Added at 20 Ok Reg 2479, eff 1-1-04.

NABP*LAW* 10/2013

Oregon

/OREGON/OREGON State Board Regulations/OR BReg Chapter 855. Board of Pharmacy/OR BReg Division 19. Licensing of Pharmacists/Pharmacist-In-Charge/OR BReg 855-019-0300. Duties of a Pharmacist-in-charge.

OR BReg 855-019-0300.
Duties of a Pharmacist-in-charge.

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a Board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the Board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;

(f) If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

History: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10
NABP*LAW* 09/2013

/OREGON/OREGON State Board Regulations/OR BReg Chapter 855. Board of Pharmacy/OR BReg Division 41. Operation of Pharmacies (Retail and Institutional Drug Outlets) Consulting Pharmacists and Operation of Drug Rooms/OR BReg General/OR BReg 855-041-1020 Security of Prescription Area

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OR BReg 855-041-1020
Security of Prescription Area

(1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to ensure the security of those drugs.

(2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.

(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-

pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041- 2100.

(4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.

(5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041- 6310, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such security system, as approved by the Board, shall be maintained in the pharmacy.

History: Hist.: 1PB 5-1982, f. & ef. 8-6-82; PB 1-1987, f. & ef. 2-3-87; Renumbered from 855-041-0026, BP 7-2012, f. & cert. ef. 12-17-12

NABP*LAW* 09/2013

/OREGON/OREGON State Board Regulations/OR BReg Chapter 855. Board of Pharmacy/OR BReg Division 41. Operation of Pharmacies (Retail and Institutional Drug Outlets) Consulting Pharmacists and Operation of Drug Rooms/OR BReg Controlled Substances/OR BReg 855-041-6600 Controlled Drug Accountability

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OR BReg 855-041-6600
Controlled Drug Accountability

(1) The hospital must establish procedures and maintain records to account for all controlled substances and any other drugs designated by the appropriate hospital committee. Records must include:

(a) Name of drug;

(b) Dose ordered, dose dispensed, and dose administered;

(c) Identity of patient;

(d) Date and time of administration;

(e) Person administering the drug;

(f) Verification and documentation of any wasted drug including partial doses.

(2) The pharmacy must provide separately locked, securely affixed compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single-unit

packaged drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(3) The pharmacy must obtain a delivery receipt for all controlled drugs supplied as floor-stock. This record must include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the distributing pharmacist and the receiving nurse.

(4) A record must be kept of each administration of a controlled drug from floor-stock. The record must be returned to the pharmacy monthly and the PIC or designee must:

(a) Match returned records with delivery receipts to verify that all records are returned;

(b) Periodically audit administration records for completeness;

(c) Reconcile administration records with inventory and verify that sums carried from one record to the next are correctly recorded;

(d) Periodically verify that doses documented on administration records are reflected in the medical record; and

(e) Initial the returned record and file by date of issue.

History: Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

NABP*LAW* 09/2013

Rhode Island

/RHODE ISLAND/RHODE ISLAND Rules and Regulations /RI BReg Title 31. Health Department/RI BReg Division 2. Drug Control/RI BReg Rule 8. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors/RI BReg Part III. Pharmacies: Licensure Requirements/RI BReg 31-2-8:13.0. General Requirements: All Pharmacies

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RI BReg 31-2-8:13.0.
General Requirements: All Pharmacies

13.1 ***Personnel:*** A licensed pharmacist shall be physically accessible at the address listed on the license in order to operate and manage the pharmacy at all times during the hours of operation when the pharmacy is open to the public. The pharmacist(s) shall be subject to all the statutory and regulatory provisions herein pertaining to the practice of pharmacy.

13.1.1 The owner shall ensure that a sufficient number of qualified, trained, competent and adequately supervised pharmacists and supportive personnel are employed to provide technical

services, as well as ensuring that all such functions and activities are performed competently, safely, and without risk of harm to patients. The relationship between the supervising pharmacist and the supportive personnel shall be such that the pharmacist is fully aware of and responsible for all activities involved in the preparation and dispensing of medications prior to the release to the patient, including the maintenance of appropriate records.

13.1.2 The pharmacy shall be directed by a licensed pharmacist, hereinafter referred to as the pharmacist-in-charge, who shall be responsible for meeting the requirements set forth by federal and state law, this section, and other applicable regulations of the Board. The pharmacist-in-charge shall be thoroughly familiar with the specialized functions of pharmacy practice.

13.1.3 The pharmacist-in-charge shall ensure that a sufficient number of pharmacists and supportive personnel are available to operate such pharmacy competently, safely, and to meet the needs of patients. All pharmacists shall be properly identified by name and licensure designation.

13.1.4 The owner shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.

13.1.5 The pharmacist-in-charge of a pharmacy shall be responsible for no less than the following:

(a) Provide to the Department a beginning inventory of all controlled substances, Schedules II-V, upon commencement of duties, and an ending inventory of same upon termination of duties as pharmacist-in-charge;

(b) Maintain adequate controls to prohibit the diversion of controlled substances and promptly execute DEA Form 106 (or its successor form) to the Drug Enforcement Administration and the Department in the event of a theft or loss of a controlled substance;

(c) Report prescription forgeries, or attempted forgeries, as deemed necessary in the professional judgment of the pharmacist-in-charge, to the appropriate law enforcement authorities;

(d) Ensure that the pharmacy dispensing area and equipment is in clean and orderly condition, that all licenses and registrations are current, that the "top ten" list and prices are conspicuously posted, and that the expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed;

(e) Remove all controlled and non-controlled drugs from any pharmacy or institution upon sale or closure of the facility;

(f) Comply with the *Rules and Regulations Governing the Disposal of Legend Drugs* (*R21-31-LEG*) promulgated by the Department, to utilize an alternative drug destruction mechanism for expired, excess/undesired controlled substances consistent with all federal and state laws and regulations;

(g) Contact the Department whenever a concern arises that would affect the pharmacy's practice;

(h) Ensure adherence to all policies and procedures for the operation of the pharmacy in accordance with the Act and the rules and regulations herein;

(i) Be administratively responsible for the overall operation and conduct of the pharmacy.

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History: Amended Feb. 4, 2010; May 10, 2012.

NABP*LAW* 09/2013

Tennessee

/TENNESSEE/TENNESSEE Board of Pharmacy Regulations/TN BReg Chapter 1140-3. Standards of Practice/TN BReg 1140-3-.09. Loss of prescription drugs, devices, and related materials.

TN BReg 1140-3-.09.
Loss of prescription drugs, devices, and related materials.

The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.

History: Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

NABP*LAW* 10/2013

Texas

/TEXAS/TEXAS Pharmacy Rules and Regulations/TX BReg Texas Pharmacy Rules TAC Title 22, Part 15/TX BReg Chapter 291. Pharmacies/TX BReg Subchapter B. Community Pharmacy (Class A)/TX BReg 291.32. Personnel

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TX BReg 291.32.
Personnel

(a) Pharmacist-in-charge.

(1) General.

(A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously; or

(ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(B) The pharmacist-in-charge shall comply with the provisions of § 291.17 of this title (relating to Inventory Requirements).

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) educating and training of pharmacy technicians and pharmacy technician trainees;

(B) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(C) disposing of and distributing drugs from the Class A pharmacy;

(D) storing all materials, including drugs, chemicals, and biologicals;

(E) maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(i) consulting with the owner concerning and adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated pharmacy dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated pharmacy dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

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History: The provisions of this §291.32 adopted to be effective September 14, 1988, 13 TexReg 4306; amended to be effective October 27, 1989, 14 TexReg 5494; amended to be effective September 5, 1990, 15 TexReg 4807; amended to be effective January 29, 1992, 17 TexReg 323; amended to be effective January 1, 1993, 17 TexReg 9116; amended to be effective September 30, 1993, 18 TexReg 6460; amended to be effective June 1, 1994, 19 TexReg 3921; amended to be effective March 21, 1996, 21 TexReg 2227; amended to be effective April 7, 1997, 22 TexReg 3106; amended to be effective September 16, 1999, 24 TexReg 7227; amended to be effective March 29, 2000, 25 TexReg 2575; amended to be effective June 4, 2000, 25 TexReg 4778; amended to be effective August 31, 2000, 25 TexReg 8405; amended to be effective December 27, 2000, 25 TexReg 12690; amended to be effective September 12, 2001, 26 TexReg 6891; amended to be effective September 8, 2002, 27 TexReg 8214; amended to be effective June 23, 2003, 28 TexReg 4637; amended to be effective March 4, 2004, 29 TexReg 1951; amended to be effective June 6, 2004, 29 TexReg 5361; amended to be effective September 18, 2007, 32 TexReg 6319; amended to be effective September 7, 2008, 33 TexReg 7218; amended to be effective September 13, 2009, 34 TexReg 6112; amended to be effective May 30, 2010, 35 TexReg 4165; amended to be effective December 8, 2010, 35 TexReg 10690; amended to be effective September 12, 2011, 36 TexReg 5847; amended to be effective June 7, 2012, 37 TexReg 4046; amended to be effective March 17, 2013, 38 TexReg 1682.

NABP*LAW* 10/2013

/UTAH/UTAH Board of Pharmacy Rules/UT BReg R156. Commerce. Occupational and Professional Licensing/UT BReg R156-17b. Pharmacy Practice Act Rule /UT BReg R156-17b-603. Operating Standards--Pharmacist-in-charge.

UT BReg R156-17b-603.
Operating Standards--Pharmacist-in-charge.

(1) The PIC shall have the responsibility to oversee the operation of the pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, durable medical equipment and medical supplies. The PIC shall be personally in full and actual charge of the pharmacy.

(2) In accordance with Subsection 58-17b-103(1) and 58-17b-601(1), a secure email address shall be established by the PIC or responsible party for the pharmacy to be used for self-audits or pharmacy alerts initiated by the Division. The PIC or responsible party shall notify the Division of the pharmacy's secure email address initially as follows:

(a) at the September 30, 2013 renewal for all licensees; and

(b) thereafter, on the initial application for licensure.

(3) The duties of the PIC shall include:

(a) assuring that pharmacists and pharmacy interns dispense drugs or devices, including:

(i) packaging, preparation, compounding and labeling; and

(ii) ensuring that drugs are dispensed safely and accurately as prescribed;

(b) assuring that pharmacy personnel deliver drugs to the patient or the patient's agent, including ensuring that drugs are delivered safely and accurately as prescribed;

(c) assuring that a pharmacist, pharmacy intern or pharmacy technician communicates to the patient or the patient's agent information about the prescription drug or device or non-prescription products;

(d) assuring that a pharmacist or pharmacy intern communicates to the patient or the patient's agent, at their request, information concerning any prescription drugs dispensed to the patient by the pharmacist or pharmacy intern;

(e) assuring that a reasonable effort is made to obtain, record and maintain patient medication records;

(f) education and training of pharmacy technicians;

(g) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;

(h) disposal and distribution of drugs from the pharmacy;

(i) bulk compounding of drugs;

(j) storage of all materials, including drugs, chemicals and biologicals;

(k) maintenance of records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and regulations;

(l) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for such drugs;

(m) if records are kept on a data processing system, the maintenance of records stored in that system shall be in compliance with pharmacy requirements;

(n) legal operation of the pharmacy including meeting all inspection and other requirements of all state and federal laws, rules and regulations governing the practice of pharmacy;

(o) assuring that any automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards;

(p) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;

(q) assuring that all relevant information is submitted to the Controlled Substance Database in the appropriate format and in a timely manner;

(r) assuring that all personnel working in the pharmacy have the appropriate licensure;

(s) assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy technician/pharmacy intern/support personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

(t) assuring that the PIC assigned to the pharmacy is recorded with the Division and that the Division is notified of a change in PIC within 30 days of the change; and

(u) assuring with regard to the secure email address used for self-audits and pharmacy alerts that:

(i) the pharmacy uses a single email address; and

(ii) the pharmacy notifies the Division, on the form prescribed, of any change in the email address within seven calendar days of the change.

NABP*LAW* 08/2013

Vermont

/VERMONT/VERMONT Pharmacy Regulations/VT BReg Title 20. Secretary of State/VT BReg Subtitle 4. Office of Professional Regulation - Board of Pharmacy/VT BReg Part 6. Pharmacist-Manager/VT BReg 20-4-1400:6.3. Duties Included

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VT BReg 20-4-1400:6.3.
Duties Included

The current or proposed pharmacist-manager shall:
(a) be responsible for proper closing of the drug outlet; or if a foreclosure or bankruptcy, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacy-manager.

(b) be responsible for required record keeping of drugs and devices that are destroyed, surrendered to the Board, or returned to the wholesaler or manufacturer for disposal.

(c) be responsible for enforcing security standards for the prescription area.

(d) ensure that all policies and procedures are in computerized form or if written shall be collected in a format such as a three-ring binder that can be easily accessed, updated and revised as necessary.

(e) assure that the automated pharmacy dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(f) implement an ongoing quality assurance program that monitors performance of the automated pharmacy dispensing system, which is evidenced by written policies and procedures adopted by the pharmacy.

(g) assure that all pharmacists employed at the pharmacy are properly licensed, all pharmacy technicians are properly registered, and that all pharmacy interns employed at the pharmacy are properly registered with the Board of Pharmacy.

(h) report to the Board within 10 days, along with supporting information and evidence, any disciplinary action taken by it or its staff, after an initial investigation, or hearing in which a pharmacist, pharmacist intern, or pharmacy technician has been afforded the opportunity to

participate, which limits or suspends, conditions, or terminates that person's employment for drug diversion or violations of the rules and statutes governing pharmacy practice. If the pharmacy manager is disciplined, the pharmacy owner shall report the action to the board.

(i) Notify the Board of Pharmacy immediately of any of the following changes on forms provided by the Board:

(1) Any theft or significant loss of prescription drugs shall be reported to the Board immediately by telephone, email or fax. Within three days, a written report shall be made on forms available from the Board and on line for this purpose;

(2) Change of ownership of the pharmacy, including the filing of a new application for licensure by the owner, corporate officer of partner;

(3) Change of address of the pharmacy, or if change of location, including the filing of a new application;

(4) In the event of bankruptcy or foreclosure, the official in charge shall obtain the services of a pharmacist to serve as acting pharmacist-manager;

(5) Permanent closing of the pharmacy; and

(6) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the Board;

(j) Make or file any reports required by state or federal laws and rules;

(k) Respond to the Board of Pharmacy regarding any violations brought to his or her attention;

(l) Establish policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying the existence thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures;

(m) Provide the Board with prior written notice of the installation or removal of automated pharmacy systems. The notice must include, but is not limited to:

(1) The name and address of the pharmacy;

(2) The name and location of the automated equipment; and
(
3) The identification of the responsible pharmacist.
History: Adopted Oct. 1, 2009.

NABP*LAW* 10/2013

/VIRGINIA/VIRGINIA Pharmacy Practice Regulations/VA BReg Title 18. No. 110. Chapter 20. Regulations of the Board of Pharmacy/VA BReg Part IV. Pharmacies/VA BReg 18 VAC 110-20-110. Pharmacy Permits Generally.

VA BReg 18 VAC 110-20-110.
Pharmacy Permits Generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

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.

C. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

D. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

F. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a

private dwelling or residence after September 2, 2009.

NABP*LAW* 07/2013

/VIRGINIA/VIRGINIA Pharmacy Practice Regulations/VA BReg Title 18. No. 110. Chapter 20. Regulations of the Board of Pharmacy/VA BREG PART XI. Unit Dose Dispensing Systems/VA BReg 18 VAC 110-20-440. Responsibilities of the Pharmacist-in-charge.

VA BReg 18 VAC 110-20-440.
Responsibilities of the Pharmacist-in-charge.

A. The PIC in a pharmacy located within a hospital or the PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18 VAC 110-20-140 and shall ensure compliance with subsections B through G of 18 VAC 110-20-150, 18 VAC 110-20-160, 18 VAC 110-20-170, 18 VAC 110-20-180 and 18 VAC 110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to nonpharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;
2. Irrigation solutions;
3. Contrast media;
4. Medical gases;
5. Sterile sealed surgical trays that may include a Schedule VI drug; and
6. Blood components and derivatives, and synthetic blood components and products that are classified as prescription drugs.

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Washington

/WASHINGTON/WASHINGTON State Board of Pharmacy Regulations/WA BReg Title 246. Department of Health/WA BReg Chapter 246-904. Health Care Entities/WA BReg 246-904-030. Pharmacist in charge.

WA BReg 246-904-030.
Pharmacist in charge.

Every health care entity licensed under this chapter shall designate a pharmacist in charge. The pharmacist in charge may be employed in a full-time capacity or as a pharmacist consultant. The pharmacist in charge must be licensed to practice pharmacy in the state of Washington. The pharmacist in charge designated by a health care entity shall have the authority and responsibility to assure that the area(s) within the health care entity where drugs are stored, compounded, delivered or dispensed are operated in compliance with all applicable state and federal statutes and regulations.

It shall be the responsibility of the pharmacist in charge:

(1) To create and implement policy and procedures relating to:

(a) Purchasing, ordering, storing, compounding, delivering, dispensing or administering of controlled substances or legend drugs.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal regulations.

(c) Adequate security of legend drugs and controlled substances.

(d) Controlling access to controlled substances and legend drugs.

(2) To assure that the Washington state board of pharmacy is in possession of all current policies and procedures identified in subsection (1) of this section.

(3) To execute all forms for the purchase and order of legend drugs and controlled substances.

(4) To verify receipt of all legend drugs and controlled substances purchased and ordered by the health care facility.
History: Statutory Authority: RCW 18.64.450. 97-02-015, S 246-904-030, filed 12/20/96, effective 1/20/97.

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West Virginia

/WEST VIRGINIA/WEST VIRGINIA BOARD OF PHARMACY REGULATIONS/WV BReg Title 15. Board of Pharmacy/WV BReg Series 1. Licensure and Practice of Pharmacy/WV BReg 15-1-20. Duties and Responsibilities of the Pharmacist-in-Charge.

WV BReg 15-1-20.
Duties and Responsibilities of the Pharmacist-in-Charge.

20.1. A pharmacy may not operate without a pharmacist-in-charge (hereinafter "PIC"), who shall be designated on the application for a pharmacy license, and in each license renewal. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time; Provided that, he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a PIC in another pharmacy.

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;

20.2.c. Implementing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;

20.2.d. The PIC shall implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he or she is in charge. He or she shall supervise a training program conducted pursuant to the training manual for all individuals employed by the pharmacy who will assist in the practice of pharmacy. The PIC shall maintain a record of all technicians successfully completing the pharmacy's technician training program and shall attest to the Board,

in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board;

20.2.e. Implementing policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

20.2.f. Assuring that all pharmacists and interns employed at the pharmacy are currently licensed and that all pharmacy technicians employed at the pharmacy are currently registered with the board;

20.2.g. Notifying the board immediately of any of the following changes:

20.2.g.1. Change of employment or responsibility as the PIC;

20.2.g.2. Change of ownership of the pharmacy;

20.2.g.3. Change of address of the pharmacy; or

20.2.g.4. Permanent closing of the pharmacy;

20.2.h. Making or filing any reports required by state or federal laws, rules, and regulations;

20.2.i. Responding to the board regarding any warning notice issued by the Board. The Board shall provide notification of the issuance of the warning notice to the pharmacy permit holder;

20.2.j. Implementing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying their existence and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures; and

20.2.k. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. The notice shall include, but is not limited to:

20.2.k.1. The name and address of the pharmacy;

20.2.k.2. The location of the automated equipment; and

20.2.k.3. The identification of the responsible pharmacist.

20.3. The PIC shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

20.3.a. The PIC shall maintain and file with the Board, on a form provided by the Board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

20.3.b. The PIC shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall specify that pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of pharmacy technicians, and that pharmacy technicians are not assigned duties that may be performed only by a pharmacist.

NABP*LAW* 09/2013

Wyoming

/WYOMING/WYOMING State Board of Pharmacy Regulations/WY BReg Department of Administration and Information - Board of Pharmacy./WY BReg Chapter 2: General Practice of Pharmacy Regulations/WY BReg Chapter 2 Section 9. Pharmacist-in-Charge.

WY BReg Chapter 2 Section 9.
Pharmacist-in-Charge.

Every licensed pharmacy must be in the continuous daily charge of a pharmacist. A pharmacist shall be designated as the Pharmacist-in-Charge and shall have direct control of the pharmaceutical affairs of said pharmacy. A pharmacist may not serve as the Pharmacist-in-Charge unless said pharmacist is physically present in the pharmacy a minimum of thirty-two (32) hours per week, every week, or eighty (80) percent of the time the pharmacy is open, if opened less than forty (40) hours per week.

A pharmacist may not serve as Pharmacist-in-Charge (PIC) for more than one pharmacy at a time. The name of the PIC shall be designated on the application of the pharmacy for the license and in each renewal period. A pharmacist may seek a waiver from the Board to serve as PIC for more than one pharmacy, provided those requirements for number of hours physically present in the pharmacy are met.

It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy license to notify the Board immediately of the disability for a period exceeding thirty (30) days of the Pharmacist-in-Charge and a new Pharmacist-in-Charge shall be designated.

(a) A corporation or other non-pharmacist owner must comply strictly with the above provisions and provide a Pharmacist-in-Charge who will have complete control over the pharmaceutical affairs of said pharmacy.

(b) Responsibility as the Pharmacist-in-Charge (PIC) includes requiring that all federal and State pharmacy laws and regulations are complied with and enforced. It shall be the duty of the PIC to report all pharmacy violations within their facility to the Board, with the single exception that, whenever PIC or staff pharmacist reports a pharmacist or pharmacy technician to the Wyoming Professional Assistance Program (WPAP) for suspected substance abuse, no further reporting to

the Board regarding the name of the suspected substance abuse impaired pharmacist or pharmacy technician needs to be done. Any pharmacy technician-in-training or pharmacy intern suspected of substance abuse and reported to WPAP shall be reported to the Board.

(c) Additional responsibilities of the Pharmacist-in-Charge shall be to:

(i) Establish policies and procedures for the procurement, storage, compounding, and dispensing of pharmaceuticals.

(ii) Supervise the professional employees of the pharmacy.

(iii) Supervise the non-professional employees of the pharmacy.

(iv) Establish and supervise the recordkeeping for the security of all pharmaceuticals.

(v) Report any significant loss or theft of drugs to the Board and other authorities.

(vi) Ensure that all staff, i.e., registered pharmacists, interns, pharmacy technicians-in-training, and registered pharmacy technicians, have valid licenses or registrations in good standing, and that all certificates are on display.

(vii) Ensure that all pharmacy licenses, including State and federal controlled substances registrations, are valid and posted.

(viii) Develop and implement a procedure for drug recall.

(ix) Be in full and actual charge of such pharmacy and responsible for whatever goes on in it.

(x) Develop a written policy for delivery of prescription drugs during non-pharmacy hours which shall include, but not be limited to:

(A) An arrangement made ahead of time with the customer that delivery will occur under these circumstances.

(B) An arrangement which guarantees that the offer to counsel and, if accepted, counseling will occur on all new prescriptions.

(C) An arrangement which guarantees the security of the drugs and the confidentiality for the customer.

(D) A plan which provides that such delivery is used only when required by the customer and not used in all instances for delivery after closing hours.

(xi) Assure that all expired drug products are removed from active stock and placed in an area designated for return.

(d) No pharmacy shall be permitted to operate without a Pharmacist-in-Charge (PIC). The Board shall be notified in writing of any newly designated PIC. The Board shall record the PIC change

and issue an amended license.

NABP*LAW* 10/2013

Virginia Board of Pharmacy
PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

Upon taking over responsibility as PIC:

- You are not a PIC until the Board approves your signed application. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Once you are approved as PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit

within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on 4/30 annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of all Schedule II – V controlled substances on the date you first engage in business as the PIC. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business that day. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy, calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification.

- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -4° and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Upon leaving as PIC:

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.

- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
www.dhp.virginia.gov/pharmacy

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov (email)

APPLICATION FOR A PHARMACY PERMIT

Check Appropriate Box(es):

☐ New[3]	$270.00	☐ Change of Pharmacist-In-Charge[2]	$50.00
☐ Change of Ownership[2]	$50.00	☐ Change of Location[3]	$150.00
☐ Change of Pharmacy Name[2]	No Fee	☐ Remodeling of Prescription Dept.[3]	$150.00
☐ Reinstatement[1], possibly 3			

[1] If reinstatement, due to: ☐ Lapse of Permit or ☐ Suspension or Revocation of a Permit

The required fees must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials

Name of Pharmacy	Area Code and Telephone Number	
Street Address	Area Code and Fax Number	
City	State	Zip Code
If a current pharmacy permit is held, indicate the permit number **0201-**	Area Code and Telephone Number (currently working number)	
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming)	License Number of the PIC **0202-**	
Signature of the Pharmacist-In-Charge (PIC) (if change of PIC, incoming signature)- By affixing my signature I acknowledge that I have read and understood guidance document 110-27 and associated information regarding the inspection process.	Effective Date of Change (if change of PIC, date assuming role as PIC) [2]	
	Date	

Expected Hours of Operation	Expected Opening, Moving, or Completion Date	Requested Inspection Date [3]

[3] **A 14-day notice is required for scheduling an opening or change of location inspection. Drugs may not be stocked prior to inspection and approval.** An inspector will call prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

FOR BOARD USE ONLY: Acknowledgement of Inspection Request

Date Processed: _____ **Assigned Inspection Date[3]:** _____

Application Number Assigned	Date Inspected	Permit Number	Date Issued
0201-		0201-	

OWNERSHIP TYPE—check one: Corporation ☐ Partnership ☐ Individual ☐ Other ☐

Name of ownership entity if different from name of application:

Street Address: Phone No.

City: State: Zip Code:

State(s) of incorporation:

List all other trade or business names used by this facility

Name: _____ **Name:** _____

Name: _____ **Name:** _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED ☐

Name: _____ Title: _____

Residence Address: _____

Name: _____ Title: _____

Residence Address: _____

Name: _____ Title: _____

Residence Address: _____

LIST OF PHARMACISTS PRACTICING AT THIS PHARMACY OTHER THAN PIC OR LIST IS ATTACHED ☐

Name: _____ License No. **0202-**

Name: _____ License No. **0202-**

Name: _____ License No. **0202-**

Name: _____ License No. **0202-**

Name: _____ License No. **0202-**

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