

## **BOARD OF PHARMACY INSPECTION PLAN**

### **I. STATUTORY AUTHORITY**

- A Section 54.1-3307, 54.1-3308 and 54.1-3404.1, Code of Virginia: Section 54.1-3307 gives the Board power and authority to regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or other disposal of drugs, cosmetics, and devices. Section 54.1-3308 gives the Board the power to inspect drugs, cosmetics, and devices, and, for this purpose, the right to inspect any pharmacy or other place where drugs, cosmetics, or devices are stored or dispensed. Section 54.1-3404.1 gives the Board the authority to license and regulate practitioners to sell controlled substances.
- B Board of Pharmacy Regulation 18VAC 110-20-10 and 110-30-10: These regulations establish standards for the practice of pharmacy and for manufacturing and distributing drugs, cosmetics, and devices pursuant to § 54.1-3407.
- C Sections 54.1-2505(9) and 54.1-2506, Code of Virginia: These sections require the Director of the Department to enforce the boards' laws and regulations.

### **II. BACKGROUND DISCUSSION**

- A. Board of Pharmacy: The Board, by § 54.1-3307 of the Code, establishes standards of conduct for the practice of pharmacy and distribution of drugs.
- B. Probation and Inspection Unit: The Probation and Inspection Unit of the Department was established on July 1, 1986. The Unit inspects and, by request, monitors compliance by licensees with sanctions and terms of board orders. The Unit also conducts background investigations on request for reinstatement or upon application of licensure.
- C. Inspection Plan: This plan was developed by the Department in conjunction with the Board to establish procedures to be followed for selecting, conducting, and reporting inspections of establishments licensed by the Board.

### **III. OBJECTIVE**

To obtain compliance with the regulations and laws governing the practice of pharmacy and the distribution of drugs by inspecting approximately 750 annually.

### **IV. TYPE OF FACILITIES SUBJECT TO INSPECTION**

There are approximately 2572 total licensed establishments. Nine categories of permits are issued.

- A. Pharmacy: A pharmacy is an establishment where or out of which pharmacy is practiced.

There are approximately 1576 licensed pharmacies that are subjected to inspection. Four types of pharmacies are subjected to inspections.

- 1. Community Pharmacy (Retail): A community pharmacy is any pharmacy where drugs are dispensed and offered for sale at retail. Patients are primarily ambulatory (walk-in). There are approximately 1456 licensed community pharmacies that are subject to inspection. It requires an average of 2.5 hours on-site and one-hour travel time to conduct an inspection of a community pharmacy.

2. Hospital Pharmacy: A hospital pharmacy is any pharmacy located within an institution where drugs are dispensed to institutionalized patients of that institution. There are approximately 120 licensed hospital pharmacies that are subject to inspection. It requires an average of four hours on-site and one-hour travel time to conduct an inspection of a hospital pharmacy.
  3. Nuclear Pharmacy: A nuclear pharmacy is any pharmacy providing radiopharmaceutical services. There are approximately three nuclear pharmacies that are subject to inspection. It requires an average of 1.5 on-site hours and one-hour travel time to conduct an inspection of a nuclear pharmacy.
  4. Special or Limited-use Pharmacy: A limited used pharmacy is any pharmacy where or out of which the scope of pharmacy practice is limited. An example is a practice limited to substance abuse.
- B. Physicians Licensed to Dispense Drugs: Physicians licenses to dispense drugs are subject to an inspection. There are approximately 22 physicians licensed to dispense drugs that are subject to an inspection. It requires on average 1.5 on-site hours and one hour of travel time to conduct an inspection of a physician licensed to dispense drugs.
  - C. Licensed Humane Societies and Animal Shelters: A licensed humane society and animal shelter is any establishments licensed by the board to purchased and administer Sodium Pentobarbital to euthanize animals. There are approximately 68 licensed humane societies and animal shelters to an inspection. It requires an average of one hour on-site and one hour of travel time to conduct an inspection of a humane society or animal shelter
  - D. Wholesale distributor: A wholesale distributor is any establishment, including a manufacturer, distributing and selling drugs to any person who is not the ultimate user or consumer. There are approximately 148 wholesale distributors subject to an inspection. It requires an average of two hours on-site and one-hour travel time to conduct an inspection of a wholesale distributor.
  - E. Medical Equipment Supplier: A medical equipment suppliers is any person engaged in the delivery to the ultimate hypodermic syringes and needles, medicinal oxygen, Schedule IV controlled devices and those Schedule VI controlled substances with no medicinal properties which are used for cleaning for medical equipment. There are approximately 181 medical equipment suppliers subject to an inspection so requires an average of one-hour on-site and one hour travel time to conduct an inspection of a medical equipment supplier.
  - F. Warehouser: A warehouser is any person other than a wholesales distributor engaged in selling or distributing prescription drugs or devices to any person who is not an ultimate user or consumer. There are approximately 19 warehouser subject to an inspection. It requires an average of one-hour on-site and one-hour travel time to conduct an inspection of a warehouser.
  - G. Manufacturer: A manufacturer is any person who produces or prepares any drug by extraction, combination, or repackaging. There are approximately 85 licensed manufacturers. Two categories of permits are issued:
    1. Nonrestricted Manufacturing Permit: A Nonrestricted manufacturer is any person manufacturing any drug, proprietary medicine, cosmetic, or devices.  
  
There are approximately 20 nonrestricted manufacturer subject to an inspection. It requires and average of two on-site hours and one hour travel time to conduct an inspection of a nonrestricted manufacturer.
    2. Restricted Manufacturing Permit: A restricted manufacture is any person manufacturing only a proprietary medicine or cosmetic. An example is an establishment manufacturing or repackaging oxygen.

There are approximately 65 restricted manufacturers subject to an inspection. It requires an average of two hours on-site and one-hour travel time to conduct an inspection of a restricted manufacturer.

- H. Practitioners licensed to sell control substances: A practitioner of medicine, osteopath, or podiatry licensed by the Board of Pharmacy to sell control substances.

There are approximately 240 practitioners licensed to sell controlled substances subject to an inspection. It requires an average of 1.5 on-site and one- hour travel time to conduct an inspection of a practitioner licensed to sell controlled substances.

- I. Controlled Substances Registration for other Persons or Entities: A person or entity as outlined in Board of Pharmacy Regulation 18VAC 110-20-690 who maintains a supply of Schedule II through Schedule V controlled substances.

There are approximately 10 persons or entities registered by the Board subject to an inspection. It requires an average of 1.5 on-site and one- hour travel time to conduct a Controlled Substance Registration inspection.

## V TYPES OF INSPECTION

- A. New: Establishments which have made application to the Board for any category of establishment permit are required to be inspected prior to opening to determine if all requirements are met. These inspections will be announced. Approximately 50 new establishment inspections each year will be conducted.

- B. Routine Inspection: These are conducted to determine if the establishments continue to meet the requirement.

Routine inspections are unannounced.

The frequency of routine inspections is discussed in Section VII of this plan.

Approximately 605 routine inspection will be conducted each year.

- C. Reinspections: Reinspections are conducted at the request of the Board as a result of deficiencies noted a previous inspection report. These inspections determine if establishments have corrected the deficiencies previously cited. The Inspection Unit will also inspect the areas outlined in Section VI.A. If the inspector observes a new violation, it shall be included in the reinspection report.

As probable cause exists from the deficiencies noted on the previous inspection report, reinspections will be unannounced.

Approximately 30 reinspections will be conducted each year.

## VI. ESTABLISHMENT INSPECTION ITEMS

- A. Routine Inspection: When conducting routine inspections, the inspector will determine the following:

- 1. Communities Pharmacies (retail):

- a. Permit/licenses (Sections 54.13314 and 54.13430, Code of Virginia):

- (1) Displayed (Section 54.1-3314 and 54.1-3430): Each permit, license, and/or certificate must be posted for public view in a common area. A common area would be the waiting area, yes or no? If no, document.
  - (2) Current (Sections 54.1-3314, 54.1-3430 and 54.1- 3434): All permits, licenses, and certificates current, yes or no? If no, document.
- b. Physical Standards for Pharmacies (Board of Pharmacy Regulation 18 VAC 110-20-150):
- (1) Space requirements [Board of Pharmacy regulation 18 VAC 110-20-150(A)]: Is the storage, compounding and preparation area at least 240 square feet, yes or no? If no, document. The inspector will measure and record the size of the prescription room on the inspection form.
  - (2) Access to Dispensing Area [Board of Pharmacy Regulation 18 VAC 110-20-150 (B)]: Is access to stock room, rest rooms, and other areas through the dispensing area, yes or no? If no, document.
  - (3) Temperature: [Board of Pharmacy Regulation 18 VAC 110-20-150(D)]: The pharmacy shall maintain a temperature between 59 and 86 degrees Fahrenheit, and shall be lighted and ventilated. The inspector will measure the temperature with a thermometer and record it on the inspection form.
  - (4) Counter Space [Board of Pharmacy regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping, yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the condition on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (5) Sink [Board on Pharmacy Regulations 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
  - (6) Refrigerator [Board of Pharmacy regulation 18 VAC 110-20-150(G)]: Refrigeration facilities with monitoring thermometers maintained within the prescription department, yes or no? If no, document.
- c. Sanitary Conditions [(Board of Pharmacy Regulation 18VAC 110-20-160)]:
- (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (2) Trash disposal facilities and receptacles, yes or no? If no, document.
- d. Required Minimum Equipment [(Board of Pharmacy Regulation 18 VAC 110-20-170)]:
- (1) Current Dispensing Information reference source, yes or no? If no, document
  - (2) Prescription Balance sensitive to 15mg., weights or an electric scale, yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board Regulation, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary, yes or no? If no, document.

- (5) Other equipment, supplies and references consistent with the scope of practice, yes or no? If no, document.
- e. Security System [Section 54-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
  - (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no. document.
  - (2) Devices maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate prescription department, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
  - (5) Alarm system controlled only by the pharmacist(s) and activated when prescription department is closed for business, yes or no? If no document.
- f. Prescription Department Enclosure [Board of Pharmacy Regulation 18 VAC 110-20-190]:
  - (1) Enclosure constructed in such a manner that it protects the controlled drug from stock from unauthorized entry whether or not a pharmacist is on duty. The inspector will describe the enclosure on the inspection form.
  - (2) Enclosure of sufficient height to prevent from reaching over and gaining access to the drug. The inspector will measure the height of enclosure and record on the inspection form.
  - (3) Entrances to enclosed area have a door with no more than a six –inch gap from the floor and which is at least as high as the adjacent counter, yes or no? If no, document.
  - (4) Doors to area have adequate locking devices. The inspector will describe the type of locking devices on the inspection form.
  - (5) Only pharmacist(s) in possession of any keys to the locking device on door to enclosure, yes or no? If no, document.
  - (6) If there is an emergency key or access code to the enclosure, is it maintained in a sealed envelope, signed by the pharmacist, and placed in safe or other secured place, yes or no? If no, document.
- g. Storage of Drugs, Devices and Controlled Paraphernalia (Board of Pharmacy Regulation 18 VAC 110-20-200):
  - (1) Prescriptions Awaiting Delivery (Board of Pharmacy Regulation 18 VAC 110-20-200(A): Prescriptions awaiting delivery to patients stored in secured place outside of dispensing area and access restricted by the pharmacist to designated clerical assistants, yes or no? If no, the inspector will describe the storage area and accessibility on the inspection form.
  - (2) The prescription delivered when pharmacist s not on duty, are written procedures maintained to outline compliance with counseling requirements of Section 54.1-3319, yes or no? If no, document.
  - (3) Safeguards for Controlled Paraphernalia (Board of Pharmacy regulation 18 VAC 110-20-200 (C): Controlled paraphernalia stored in an area where the pharmacist can exercise reasonable supervision and control, yes or no? If no, document.

- (4) Expired Drug: Security (Board of Pharmacy Regulation 18 VAC 110-20-200(D):  
Expired drugs separated from the stock used for dispensing and maintained in a designated area within the prescription department, yes or no? If no, document.
- h. Drug Inventory and records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulations 18 VAC 110-20-240):
- (1) Inventories and records of Schedule II drugs maintained separate from all other records, yes or no? If no, document.
  - (2) Inventories and records of Schedule III, IV and V drugs maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
  - (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
  - (4) Records for Schedule II through V drugs maintained at pharmacy for two years form date of transaction, yes or no? If no, document.
  - (5) Required inventories for Schedule II through V drug on-site and current?
    - (a) Biennial Inventory, Yes or no? If no document.
      - (i) Inventory dated, yes or no? If no document
      - (ii) Opening and closing of business, yes or no? If no, document.
      - (iii) Signed by person taking inventory, yes or no? If no, document
    - (b) If applicable: Change of Pharmacist-in-charge inventory, yes or no? If no, document
      - (i) Inventory dated, yes or no? If no, document.
      - (ii) Opening or closing of business, yes or no? If no, document.
      - (iii) Signed by person taking inventory, yes or no? If no, document.
  - (6) Thefts or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration, yes or no? If no document.
  - (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.
  - (8) Hardcopy of prescription maintained and filed chronologically, yes or no? If no, document.
  - (9) Prescriptions for Schedule II drug maintained in a separate prescription file, yes or no? If no, document.
  - (10) Prescription for Schedule III through V drugs maintained in a separate file, yes or no? If no, are they filed in such a form that they are readily retrievable (stamped with a red one-inch-high "C") from other prescriptions of the pharmacy and filled with Schedule VI prescriptions, yes or no? If no, indicate the number of prescriptions not filled according to regulations.

(11) Schedule II prescription include:

- (a) Patient's address, yes or no? If no, indicate the number without patient's address.
- (b) Practitioner's address, yes or no? If no, indicate the number without the patient's address.
- (c) Prescription dated, yes or no? If no, indicate the number not dated.
- (d) Prescription initialed by pharmacist, yes or no? If no, indicate the number not initialed.
- (e) Prescriptions contain practitioner's DEA number, yes or no? indicate the number with no DEA number.

(12) Schedule III, IV, V and VI prescriptions includes:

- (a) Patient's address, yes or no? If no, indicate the number without patient's address.
- (b) Practitioner's address, yes or no? If no, indicate the number without the patient's address.
- (c) Prescription dated, yes or no? If no, indicate the number not dated.
- (d) Prescriptions contain red "C", yes or no? If no, indicate the number not so marked<sup>2</sup>
- (e) Prescriptions initialed by pharmacist, yes or not? If no, indicate the number not initialed.
- (f) Prescription refilled more than five times, yes or no? If yes, indicate number refilled more than five times. Provide a listing of 10 prescription numbers to support "yes."\*
- (g) Prescriptions refilled longer than six-months, yes or no? If yes, indicate the number refilled after six months. Provide a listing of 10 prescription numbers to support "yes."
- (h) Prescription refilled dated and initialed by the pharmacist on the back of prescription, yes or no? If no, indicate the number not dated and initialed on the back.
- (i) Prescription for Schedule VI drugs refilled beyond a two-year period, yes or no? If yes, indicate the number refilled beyond two years.<sup>3</sup>

i. Automated Data processing Records of Prescriptions (Board of Pharmacy Regulation 18 VAC 110-20-250):

- (1) Hard copy prescription placed on file, yes or no? If no document.
- (2) Data system provides retrieval by original prescription information for those prescriptions currently authorized for dispensing, yes or no? If no, document.
- (3) Data system provides retrieval CRT display or printout of dispensing history for prescriptions dispensed during the past two years, yes or no? If no, document.

- (4) If the system provides a daily printout of dispensing data, is the printout verified, dated, and signed by the pharmacist who dispensed the prescription, yes or no? If no, indicate the number of printouts not verified, dated, and signed.
  - (5) If the system does not provide a daily printout, does the pharmacy maintain a bound log book or separate file verified, dated, and signed by the pharmacist as described in (3) above, yes or no? If no, document.
- j. Pharmacy Repackaging of Drugs: Records Required (Board of Pharmacy Regulation 18 VAC 119-20-355)
- (1) Control records maintained for one year or until the expiration date of drug, yes or no? If no, document.
  - (2) Records contains:
    - (a) Name of drug(s) repackaged, yes or no? If no, document.
    - (b) Strength of drug(s) repackaged, yes or no? If no, document.
    - (c) Quantity repackaged, yes or no? If no, document.
    - (d) Initials of supervising pharmacist(s), yes or no? If no, document.
    - (e) Manufacturer's or distributor's name, yes or no? If no, document.
    - (f) Control number or assigned number, yes or no? If no, document.
    - (g) Expiration date, yes or no? If no, document.
    - (h) Date repackaged, yes or no? If no document.
  - (3) Repackaged drugs labeled as follows:
    - (a) Name and strength of drug, yes or no? If no, document
    - (b) Manufacture's or distributor's name and control number or assigned control number, yes or no? I f no, document.
    - (c) Proper expiration date, yes or no? If no, document
- k. Dispensing of Schedule II Drugs. [Board of Pharmacy Regulation 18 VAC 110-20-290]:
- (1) Schedule II prescriptions dispensed more than 6 months after the issue date, yes or no? If no, document.
- l. Emergency Prescription for Schedule II Drugs:  
[Section 54.13410(A)(2) and Board of Pharmacy Regulation 18 VAC 110-20-290]:
- (1) Quantity prescribed and dispensed limited to the amount necessary to treat patient during the emergency period, yes or no? If no, indicate amount prescribed on emergency prescription.
  - (2) Written prescription s on file and attached to the emergency prescription(s), yes or no? If no, document.
- m. Partial Dispensing of Schedule II Prescriptions (Board of Pharmacy Regulation 18 VAC 110-20-310):
- (1) If Schedule II prescription are partially filled, is the remaining quantity dispensed within 72 hours, yes or no? If no, document.
  - (2) Partial dispensing of Schedule II drugs to patients in long term care facilities include:



- (a) Date of partial dispensing records on back prescription or other appropriate record, yes or no? If no, document.
  - (b) Quantity dispensed recorded on back of prescription, yes or no? If no, document.
  - (c) Remaining quantity authorized to be dispensed recorded on back of prescription, yes or no? If no, document.
  - (d) Identification of dispensing pharmacist, yes or no? If no, document.
  - (e) Total quantity dispensed did not exceed total quantity prescribed, yes or no? If no, document.
  - (f) Partial dispensing did not exceed 60 days from the issue date of the prescription, yes or no? If no, document.
- n. Partial filling of Schedule II prescription for Terminally Ill Patients [Board of pharmacy Regulation 18 VAC 110-20-310(D)]:
- (1) If Schedule II prescription are partially filled for terminally ill patients, is the illness recorded on prescription, yes or no? If no, document.
  - (2) Partial filling of Schedule II prescription for terminally ill patients include:
    - (a) Date of partial dispensing, yes or no? If no, document.
    - (b) Quantity dispensed, yes or no? If no, document.
    - (c) Remaining quantity authorized to be dispensed, yes or no? If no, document.
    - (d) Identification of dispensing pharmacy, yes or no? If no, document.
    - (e) Total quantity dispensed did not exceed total quantity prescribed, yes or no? If no, document.
    - (f) Partial dispensing did not exceed 60 days from the issue date of the prescription, yes or no? If no, document.
- o. Dispensing Schedule V Drug Where No Rx is Required (Section 54.1-3416):
- (1) Dispensed by a pharmacist directly to person requesting preparation, yes or no? If no, document.
  - (2) Record of dispensing include:
    - (a) Date of dispensing, yes or no? If no, document.
    - (b) Name and quantity preparation dispensed, yes or no? If no, document.
    - (c) Name and address of person to whom preparation was dispensed, yes or no? If no, document.
    - (d) Initials of pharmacist dispensing preparation, yes or no? If no, document.
- p. Controlled Paraphernalia: Conditions to Dispensing Devices, Item, or Substance: Records (Section 54.1-3468):
- (1) Dispensed by a pharmacist, yes or no? If no, document.
  - (2) Record of dispensing include:
    - (a) Date of dispensing, yes or no? If no, document.
    - (b) Name and quantity of devices, items, or substance dispensed, yes or no? If no, document.
    - (c) Price sold, yes or no? If no, document.
    - (d) Name and address of person to whom devices, items, or substance dispensed, yes or no? If no, document.
    - (e) Reason for purchase, yes or no? If no, document.

- (f) Initials of pharmacist dispensing devices, items, or substance, yes or no? If no, document
- q. Labeling of Prescriptions (Section 54.1-3463 and Board Regulation 18 VAC 110-20-330):

Prescriptions labeled as follows:

- (1) Name and address of dispenser, yes or no? If no, document.
- (2) Serial number and date of prescription or filling, yes or no? If no, document.
- (3) Name of prescriber, yes or no? If no, document.
- (4) Name of patient, yes or no? If no, document.
- (5) Direction for use, yes or no? If no, document.
- (6) Drug name and strength, yes or no? If no, document.
- (7) Trade or generic name and strength, where applicable, yes or no? If no, document.
- (8) Number of dosage units or millimeters dispensed, yes or no? If no, document.

- r. Packaging Standards for Dispensing Prescriptions (Section 54.13427 and Board of Pharmacy Regulation 18 VAC 110-20-340):

- (1) Prescriptions, if applicable, dispensed in special packaging (safety enclosure), yes or no? If no, document.

- s. Unit Dose Dispensing Systems (Board of Pharmacy Regulation 18 VAC 110-20-420):

If a unit dose dispensing system is utilized, the following requirements shall apply:

- (1) Equipment to house drugs to be administered is locked when unattended, yes or no? If no, document.
- (2) Drugs labeled with drug name, strength, lot number, and expiration date, when indicate, yes or no? If no, document.
- (3) Patient's individual drug drawer or tray labeled with patient's name and location, yes or no? If no, document.
- (4) Back-up dose of any given drug exceeds one unit, yes or no? If yes, document.
- (5) Record maintained for one year showing:
  - (a) Date of filling of drug cart, yes or no? If no, document.
  - (b) Location of drug cart, yes or no? If no, document.
  - (c) Initials of person who filled drug cart, yes or no? If no, document.
  - (d) Initials of the pharmacist checking drug cart, yes or no? If no, document.
- (6) A patient profile or medication card is acceptable as a dispensing record, subject to the following conditions:
  - (a) Record of dispensing entered on the profile or medication card at the time the drawer or tray is filled, yes or no? If no, document.
  - (b) Profile or medication cards containing Schedule II through V records maintained for two years, yes or no? If no, document.

- t. Compounding Sterile Pharmaceutical Products [Board of Pharmacy Regulation 18 VAC 110-20-411]: Procedure manual maintained for the compounding, dispensing and delivery of products, yes or no? If no, document. Manual include the following elements:

- (1) Personal qualifications including initial and follow-up training, yes or no? If no, document.
  - (2) Scope of compounding performed and procedures for the compounding, yes or no? If no, document.
  - (3) Procedures for maintaining and monitoring proper operating conditions, yes or no? If no, document.
  - (4) Guidelines for patient and caretaker education, if products for home use, yes or no? If no, document.
  - (5) Guidelines for assignment of beyond use dates, yes or no? If no, document.
  - (6) Separate procedures for handling cytotoxic drugs, if applicable, yes or no? If no, document.
  - (7) Separate procedures for compounding sterile products using non-sterile components or open transfer system, yes or no? If no, document.
- u. Physical and equipment requirements for Pharmacy preparing sterile products [(Board of Pharmacy Regulation 18 VAC 110-20-413)]:
- (1) Area of sufficient size to accommodate a laminar airflow hood, yes or no? If no, document.
  - (2) Area isolated from other areas and other pharmacy functions, yes or no? If no, document.
  - (3) Maintains supplies for adequate aseptic preparation of sterile products to include:
    - (a) Anti-microbial soap, yes or no? If no document
    - (b) Hot and cold water supply and easily accessible to area, yes or no? If no, document.
    - (c) Appropriate apparel for personnel, yes or no? If no, document.
    - (d) Suitable disposal containers for needles, syringes and if applicable containers for cytotoxic and infectious waste, yes or no? If no, document.
  - (4) Equipment necessary for maintaining and monitoring required storage conditions, yes or no? If no, document.
- v. Records for sterile compounding [(Board of Pharmacy Regulation VAC 110-20-416)]:  
The following additional records maintained for sterile compounding.
- (1) Date of sterile compounding, yes or no? If no, document.
  - (2) Beyond use date assigned to sterile product, yes or no? If no, document.
  - (3) Signatures, initials, or electronic identification of pharmacist compounding or of both the non-pharmacist compounding and pharmacist observing the compounding of the sterile product, yes or no? If no, document.
  - (4) Records documenting certification of clean room and laminar flow hoods, yes or no? If no, document.

- (5) Records documenting training of patient of caregiver or both in proper storage and use of product and devices used to administer, if applicable, yes or no? If no, document.
- w. Continuing Education [(Board of Pharmacy Regulation 110-20-90)]:
  - (1) Original C.E. documents maintained for two years, yes or no? If no, document.
  - (2) Inspectors to complete verification of continuing education form for C.E. compliance.
- x. Counseling [(Section 543.1-3319 of the Code of Virginia)]:
  - (1) Offer to counsel made, yes or no? If no, document.
  - (2) Record maintained to include failure to accept offer to counsel, yes or no? If no, document.

2. Hospital Pharmacies

- a. Permits/licenses [(Section 54.1-3314 and 54.1-3430, Code of Virginia )]:
  - (1) Displayed (Section 54.1-3314 and 54-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
  - (2) Current (Section 54.1-3304, 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
- b. Physical Standards for Pharmacies [(Board of Pharmacy 18 VAC 110-20-150)]:
  - (1) Space requirements [Board or Pharmacy regulation 18 VAC 110-20-150(A)]: Is the storage, compounding and preparation area at least 240 square feet, yes or no? If no, document. The inspector will measure and record the size of the prescription room on the inspection form.
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  - (3) Temperature: [Board of Pharmacy Regulation 18 VAC 110-20-150(D)]: The pharmacy shall maintain a temperature between 59 and 86 degrees Fahrenheit, and shall be well lighted and ventilated. The inspector will measure the temperature with a thermometer and record it on the inspection form.
  - (4) Counter Space [Board of Pharmacy regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping, yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the condition on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (5) Sink [Board on Pharmacy Regulations 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
  - (6) Refrigerator [Board of Pharmacy regulation 18 VAC 110-20-150(G)]: Refrigeration facilities with monitoring thermometers maintained within the prescription department, yes or no? If no, document.

- c. Sanitary Conditions (Board of Pharmacy Regulation 18VAC 110-20-160):
  - (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (2) Trash disposal facilities and receptacles, yes or no? If no, document.
- d. Required Minimum Equipment (Board of Pharmacy Regulation 18 VAC 110-20-170):
  - (1) Current Dispensing Information reference source, yes or no? If no, document
  - (2) Prescription Balance sensitive to 15mg., weights or an electric scale, yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board Regulation, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary, yes or no? If no, document.
  - (5) Other equipment supplies and references consistent with the scope of practice, yes or no? If no, document.
- e. Security System [Section 54-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
  - (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no. document.
  - (2) Devices maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate prescription department, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
  - (5) Alarm system controlled only by the pharmacist(s) and activated when prescription department is closed for business, yes or no? If no document.
- f. Prescription Department Enclosure [Board of Pharmacy Regulation 18 VAC 110-20-190]:
  - (1) Enclosure constructed in such a manner that it protects the controlled drug from stock from unauthorized entry whether or not a pharmacist is on duty. The inspector will describe the enclosure on the inspection form
  - (2) Enclosure of sufficient height to prevent from reaching over and gaining access to the drug. The inspector will measure the height of enclosure and record on the inspection form.
  - (3) Entrances to enclosed area have a door with no more than a six –inch gap from the floor and which is at least as high as the adjacent counter, yes or no? If no, document.

- (4) Doors to area have adequate locking devices. The inspector will describe the type of locking devices on the inspection form.
- (5) Only pharmacist(s) in possession of any keys to the locking device on door to enclosure, yes or no? If no, document.
- (6) If there is an emergency key or access code to the enclosure, is it maintained in a sealed envelope, signed by the pharmacist, and placed in safe or other secured place, yes or no? If no, document.

g. Expired Drugs: Security [Board of Pharmacy Regulation 18 VAC 110-20-200(D)]:

Expired drugs separated from the stock used for dispensing and maintained in a designated area within the prescription department, yes or no? If no, document.

h. Labeling of Drugs (Board of Pharmacy Regulation 18 VAC 110-20-355):

- (1) Floor stock drug label as follows:
  - (a) Name and strength of drug, yes or no? If no, document.
  - (b) Assigned lot number and expiration date, if applicable, yes or no? If no, document.
- (2) Individual patient order labeled as follows:
  - (a) Name and strength of drug, yes or no? If no, document.
  - (b) Name and location of patient, yes or no? If no, document.

i. After-hour Access of the Pharmacy (Board of Pharmacy Regulation 18 VAC 110-20-450):

- (1) Supervisory nurse has access to pharmacy, yes or no? If no, indicate title of person who has access, if applicable.
- (2) Drug available in manufacturer's original container or units prepared and labeled by the pharmacist, yes or no? If no, document.
- (3) Record of withdrawal maintained in pharmacy for one year showing:
  - (a) Date of withdrawal, yes or no? If no document.
  - (b) Patient's name, yes or no? If no, document.
  - (c) Drug name, strength, dosage, form, and dose prescribed, yes or no? If no, document.
  - (d) Number of doses removed, yes or no? If no document.
  - (e) Signature of authorized nurse, yes or no? If no, document.

j. Floor Stock Drugs [(Proof of Delivery) Board of Pharmacy Regulation 18 VAC 110-20-460(A)]:

- (1) Delivery receipts maintained for Schedule II through V drugs supply as floor stock, yes or no? If no, document.
- (2) Receipts maintained in pharmacy for two years showing:
  - (a) Date, yes or no? If no document.
  - (b) Drug name and strength, yes or no? If no, document.
  - (c) Quantity, yes or no? If no, document.

- (d) Hospital unit receiving drug, yes or no? If no document.
  - (e) Signatures of dispensing pharmacist and receiving nurse, yes or no? If no, document.
- k. Drug Inventory and records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulations 18 VAC 110-20-240):
- (1) Inventories and records of Schedule II drugs maintained separate from all other records, yes or no? If no, document.
  - (2) Inventories and records of Schedule III, IV and V drugs maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
  - (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
  - (4) Records for Schedule II through V drugs maintained at pharmacy for two years form date of transaction, yes or no? If no, document
  - (5) Required inventories for Schedule II through V drug on-site and current?
    - (a) Biennial Inventory, Yes or no? If no document.
      - (i) Inventory dated, yes or no? If no document
      - (ii) Opening and closing of business, yes or no? If no, document.
      - (iii) Signed by person taking inventory, yes or no? If no, document
    - (b) If applicable: Change of Pharmacist-in-charge inventory, yes or no? If no, document
      - (i) Inventory dated, yes or no? If no, document.
      - (ii) Opening or closing of business, yes or no? If no, document.
      - (iii) Signed by person taking inventory, yes or no? If no, document.
  - (6) Thefts or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration, yes or no? If no document.
  - (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.
- l. Distribution records [Board of Pharmacy Regulation 18 VAC 110-20-460 (B)]
- (1) Floor Stock Drugs:
    - (a) Records maintained to document the disposition/administration of Schedule II through V drugs, yes or no? If no, document.
    - (b) Records returned to pharmacy within three months of its issue, yes or no? If no, document.
    - (c) Pharmacist-in-charge or designee shall :
      - (i) Match records with delivery receipts, yes or no? If no, document.
      - (ii) Audit return records for completeness, yes or no? If no, document.
      - (iii) Initial or sign returned record, yes or no? If no, document.
      - (iv) Records maintained for two years, yes or no? If no, document.
  - (2) Individual Patient Orders [Section 54.1-3404(D)]:

- (a) Unit Dose Dispensing Systems:
- (i) Record of dispensing for Schedule II through V drugs entered on the profile of medication card at the time the medication is dispensed, yes or no? If no, document.
  - (ii) Profile or medication card containing Schedule II through V records maintained for two years, yes or no? If no, document.
- (b) Other dispensing systems:
- (i) Record of dispensing for Schedule II through V drugs entered on the drug order provided to the pharmacy at the time the drug is dispensed, yes or no? If no, document.
  - (ii) Drug orders containing Schedule II through V records maintained for two years, yes or no? If no, document.
- (3) Out –Patient Prescriptions:
- (a) Prescription for Schedule II drugs maintained in a separate prescription file, yes or no? If no, document. Schedule II prescriptions include:
    - (i) Patient’s address, yes or no? If no, indicate the number without patient’s address.
    - (ii) Practitioner’s address, yes or no? If no, indicate the number without the patient’s address.
    - (iii) Prescription dated, yes or no? If no, indicate the number not dated.
    - (iv) Prescription initialed by pharmacist, yes or no? If no, indicate the number not initialed.
    - (v) Prescriptions contain practitioner’s DEA number, yes or no? If no, indicate the number with no DEA number.
  - (b) Prescriptions for Schedule III through V drugs maintained in a separate file, yes or no? If no, are they filled in such a form that they are readily retrievable (stamped with a red One-inch-high “C”) from other prescriptions of the pharmacy and filled with Schedule VI prescription, yes or no? If no, indicate the number of prescriptions not filled according to regulations.
- (4) Schedule III, IV, V and VI prescriptions includes:
- (a) Patient’s address, yes or no? If no, indicate the number without patient’s address.
  - (b) Practitioner’s address, yes or no? If no, indicate the number without the patient’s address.
  - (c) Prescription dated, yes or no? If no, indicate the number not dated.
  - (d) Prescriptions contain red “C”, yes or no? If no, indicate the number not so marked.\*
  - (e) Prescriptions initialed by pharmacist, yes or not? If no, indicate the number not initialed.
  - (f) Prescription refilled more than five times, yes or no? If yes, indicate number refilled more than five times. Provide a listing of 10 prescription numbers to support “yes.”<sup>4</sup>
  - (g) Prescriptions refilled longer than six-months, yes or no? If yes, indicate the number refilled after six months. Provide a listing of 10 prescription numbers to support “yes.”\*
  - (h) Prescription refilled dated and initialed by the pharmacist on the back of prescription, yes or no? If no, indicate the number not dated and initialed on the back.



- (i) Prescription for Schedule VI drugs refilled beyond a two-year period, yes or no? If yes, indicate the number refilled beyond two years.<sup>5</sup>
- m. Dispensing Schedule V Drug Where No Rx is Required (Section 54.13416):
- (1) Dispensed by a pharmacist directly to person requesting preparation, yes or no? If no, document.
  - (2) Record of dispensing include:
    - (a) Date of dispensing, yes or no? If no, document.
    - (b) Name and quantity preparation dispensed, yes or no? If no, document.
    - (c) Name and address of person to whom preparation was dispensed, yes or no? If no, document.
    - (d) Initials of pharmacist dispensing preparation, yes or no? If no, document.
- n. Controlled Paraphernalia; Conditions to Dispensing Devices, Item, or Substance; Records (Section 54.1-3468):
- (1) Dispensed by a pharmacist, yes or no? If no, document
  - (2) Record of dispensing include:
    - (a) Date of dispensing, yes or no? If no, document.
    - (b) Name and quantity of devices, items, or substance dispensed, yes or no? If no, document.
    - (c) Price sold, yes or no? If no, document.
    - (d) Name and address of person to whom devices, items, or substance dispensed, yes or no? If no, document.
    - (e) Reason for purchase, yes or no? If no, document.
    - (f) Initials of pharmacist dispensing devices, items, or substance, yes or no? If no, document
- o. Pharmacy Repackaging of Drugs: Records Required (Board of Pharmacy Regulation 18 VAC 119-20-355):
- (1) Control records maintained for one year or until the expiration date of drug, yes or no? If no, document.
  - (2) Record contains:
    - (a) Name of drug(s) repackaged, yes or no? If no, document.
    - (b) Strength of drug(s) repackaged, yes or no? If no, document.
    - (c) Quantity repackaged, yes or no? If no, document.
    - (d) Initials of supervising pharmacist(s), yes or no? If no, document.
    - (e) Manufacturer's or distributor's name, yes or no? If no, document.
    - (f) Control number or assigned number, yes or no? If no, document.
    - (g) Expiration date, yes or no? If no, document.
    - (h) Date repackaged, yes or no? If no document.
  - (3) Repackaged drugs labeled as follows:
    - (a) Name and strength of drug, yes or no? If no, document
    - (b) Manufacturer's or distributor's name and control number or assigned control number, yes or no? If no, document.
    - (c) Proper expiration date, yes or no? If no, document

p. Unit Dose Dispensing Systems (Board of Pharmacy Regulation 18 VAC 110-20-420): If a unit dose dispensing system is utilized, the following requirements shall apply:

- (1) Equipment to house drugs to be administered locked when unattended, yes or no? If no, document.
- (2) Drugs labeled with drug name, strength, lot number, and expiration date, when indicate, yes or no? If no, document.
- (3) Patient's individual drug drawer or tray labeled with patient's name and location, yes or no? If no, document.
- (4) Back-up dose of any given drug exceeds one unit, yes or no? If no, document.
- (5) Record maintained for one year showing:
  - (a) Date of filling of drug cart, yes or no? If no, document.
  - (b) Location of drug cart, yes or no? If no, document.
  - (c) Initials of person who filled drug cart, yes or no? If no, document.
  - (d) Initials of the pharmacist checking drug cart, yes or no? If no, document.
- (6) A patient profile or medication card is acceptable as a dispensing record, subject to the following conditions:
  - (a) Record of dispensing entered on the profile or medication card at the time the drawer or tray is filled, yes or no? If no, document.
  - (b) Profile or medication cards containing Schedule II through V records maintained for two years, yes or no? If no, document.

q. Emergency Room (Board of Pharmacy Regulation 18 VAC 110-20-470):

- (1) Drugs in the emergency department secured from unauthorized personnel and general public, yes or no? If no, document.
- (2) Dispensing of drugs performed by a practitioner, yes or no? If no, document.
- (3) Record maintained of all drugs administered, yes or no? If no, document.
- (4) Separate record maintained on all drugs, including samples, dispensed in the emergency room showing:
  - (a) Date and time dispensed, yes or no? If no, document.
  - (b) Patient's name, yes or no? If no, document.
  - (c) Physician's name, yes or no? If no, document.
  - (d) Name of drug, strength, dosage, and quantity dispensed, yes or no? If no, document.

r. Mechanical Devices for Dispensing and Administration of Drugs (Section 54/1-3301(4) and Board Regulation 18 VAC 110-20-490): Utilization of mechanical devices shall be under the personal supervision of a pharmacist and shall include:

- (1) Prior to removal of drugs from pharmacy, a delivery record shall be generated for all drugs to be placed into automated dispensing devices to include:
  - (a) Date, yes or no? If no document.
  - (b) Drug name and dosage form, yes or no? If no, document.
  - (c) Strength and quantity, yes or no? If no, document.
  - (d) Hospital unit receiving and unique identifier for specific device necessary drug, yes or no? If no document.
  - (e) Initials of person loading device, yes or no? If no, document.
  - (f) Initials of pharmacist reviewing transaction, yes or no? If no, document.

- (2) At the time of loading, delivery records for all Schedule II through V drugs shall be:
    - (a) Signed by nurse or other person authorized to remove drugs from a specific device, yes or no? If no, document.
    - (b) Record returned to pharmacy and maintained in chronological order for two years from the date of delivery, yes or no? If no, document.
  - (3) Automated dispensing device capable of producing a hard copy record of distribution to include:
    - (a) Patient's name, yes or no? If no, document.
    - (b) Drug name and strength, yes or no? If no, document.
    - (c) Dose withdrawn, yes or no? If no, document.
    - (d) Dose to be administered, yes or no? If no, document.
    - (e) Date and time of withdrawal, yes or no? If no, document.
    - (f) Identity of person withdrawing the drugs, yes or no? If no, document.
  - (4) Monthly audit of all distribution and administration of Schedule II through V drugs conducted, yes or no? If no, document.
    - (a) Initialed and dated, yes or no? If no, document.
    - (b) Maintained for two years, yes or no? If no, document.
  - (5) Automated dispensing device used for the dispensing of drugs from the emergency room, distinguishes dispensing from administration and identifies physician dispensing, if applicable, yes or no? If no, document.
- s. Certified Emergency Medical Technician Program (Board of Pharmacy Regulation 18 VAC 110-20-500):
- (1) Drug kit sealed in such a manner to prevent any loss of drugs, yes or no? If no, document.
  - (2) Drugs administered by a technician upon an oral order of a medical practitioner reduced to writing by the technician and signed by the physician, yes or no? If no, document.
  - (3) Record signed by the physician for drugs administered accompanies the open kit when exchanged, yes or no? If no, document.
  - (4) Record of drugs administered from kit maintained as a part of the pharmacy records pursuant to state regulations, yes or no? If no, document.
3. Nuclear Pharmacies (Board of Pharmacy Regulation 18 VAC 110-20-220):
- a. Permits/Licenses (Section 54.1-3314 and 54.1-3430, Code of Virginia):
    - (1) Displayed (Section 54.1-3314 and 54.1-3430): Each permit, licenses and certificates must be posted for public view in a common area. A common area would be the pharmacy reception area, yes or no? If no document.
    - (2) Current (Section 54.1-3304 and 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
  - b. Physical Standards for Pharmacies (Board of Pharmacy Regulation 18 VAC 110-20-150):
    - (1) Space Requirements [Board of Pharmacy Regulation 18 VAC 110-20-150 (A)]: Is the storage, compounding and preparation area at least 240 square feet, yes or no? If

no, document. The inspector will measure and record the size of the prescription room on the inspection form.

- (2) Access to Dispensing Area [Board of Pharmacy Regulation 18 VAC 110-20-150 (B)]: Is access to stock room, rest rooms, and other areas through the dispensing area, yes or no? If no, document.
- (3) Temperature [Board of Pharmacy Regulation 18 VAC 110-20-150(D)]: The pharmacy shall maintain a temperature between 59 and 86 degrees Fahrenheit, and shall be well lighted and ventilated. The inspector will measure the temperature with a thermometer and record it on the inspection form.
- (4) Counter Space [Board of Pharmacy regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping, yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the condition on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
- (5) Sink [Board on Pharmacy Regulations 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
- (6) Refrigerator [Board of Pharmacy regulation 18 VAC 110-20-150(G)]: Refrigeration facilities with monitoring thermometers if applicable, yes or no? If no, document

c. Sanitary Conditions (Board of Pharmacy Regulation 18VAC 110-20-160):

- (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
- (2) Trash disposal facilities and receptacles, yes or no? If no, document

d. Security System [Section 54-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:

- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no, document.
- (2) Devices maintained in operating order, yes or no? If no, document.
- (3) Device protects the immediate prescription department, yes or no? If no, document.
- (4) Device has an auxiliary source of power, yes or no? If no, document.
- (5) Alarm system controlled only by the pharmacist(s) and activated when prescription department is closed for business, yes or no? If no document

e. Nuclear pharmacy area separate from the pharmacy area for non-radioactive drugs, yes or no, If no, documents.

f. Nuclear pharmacy area secured from unauthorized personnel, yes or no? If no, document.

g. Separate radioactive storage and product delay area, occupying at least 25 square feet of space, yes or no? If no, document.

h. Orders for a radiopharmaceutical drug dispensed in unit-dose packages, yes or no? If no, document.

i. Immediate outside container of a radioactive drug to be dispensed labeled as followed:

- (1) Standard radiation symbol, yes or no? If no, document.
- (2) Works "Caution-Radioactive Material," yes or no? If no, document.
- (3) Name of radionuclide, yes or no? If no, document.
- (4) Chemical form, yes or no? If no, document.
- (5) Amount of radioactive material contained, yes or no? If no, document.
- (6) Requested calibration time for the amount of radioactivity contained, yes or no? If no? If no, document.
- (7) Practitioner's name and assigned lot number, yes or no? If no document.

j. Immediate inner container labeled as follows:

- (1) Standard radiation symbol, yes or no? If no, document.
- (2) "Caution-Radioactive Material", yes or no? If no, document.
- (3) Prescription number, yes or no? If no, document.

4. Special or limited-Use Pharmacy Permits (Board of Pharmacy Regulation 18 VAC 110- 20-120):

- a. The inspection items of a special or limited-use pharmacy will be determined by the scope of practice.
- b. The inspector will inspect the appropriate area as outlined in Section VI(A)(1) of this plan.

5. Permitted Physicians Licensed to Dispense Drugs (Section 54.1-3304 and Board of Pharmacy Regulation 18 VAC 110-20-410):

a. Permits/licenses (Section 54.1-3314 and 54.1-3430, Code of Virginia):

- (1) Displayed (Section 54.1-3314 and 54-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
- (2) Current (Section 54.1-3304, 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.

b. Security System [Section 54-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:

- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no. document.
- (2) Devices maintained in operating order, yes or no? If no, document.
- (3) Device protects the immediate prescription department, yes or no? If no, document.
- (4) Device has an auxiliary source of power, yes or no? If no, document.
- (5) Alarm system controlled only by the pharmacist(s) and activated when prescription department is closed for business, yes or no? If no document.

c. Drug Inventory and records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulation 18 VAC 110-20-240):

- (1) Inventories and records of Schedule II drugs maintained separate from all other records, yes or no? If no, document.
- (2) Inventories and records of Schedule III, IV and V drugs maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
- (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
- (4) Records for Schedule II through V drugs maintained at pharmacy for two years form date of transaction, yes or no? If no, document.
- (5) Required inventories for Schedule II through V drug on-site and current?

Biennial Inventory, Yes or no? If no document.

- (a) Inventory dated, yes or no? If no document
  - (b) Opening and closing of business, yes or no? If no, document.
  - (c) Signed by person taking inventory, yes or no? If no, document
- (6) Theft or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration yes or no, If no, document.
- (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.
- (8) Prescription for Schedule II drugs maintained in a separate prescription file, yes or no? If no, document.
- (9) Prescriptions for Schedule III through V drugs maintained in a separate file, yes or no? If no, are they filled in such a form that they are readily retrievable (stamped with a red One-inch-high "C") from other prescriptions of the pharmacy and filled with Schedule VI prescription, yes or no? If no, indicate the number of prescriptions not filled according to regulations.
- (10) Schedule II prescription s includes:
- (a) Patient's address, yes or no? If no, indicate the number without patient's address.
  - (b) Practitioner's address, yes or no? If no, indicate the number without the patient's address.
  - (c) Prescription dated, yes or no? If no, indicate the number not dated.
  - (d) Prescription initialed by pharmacist, yes or no? If no, indicate the number not initialed.
  - (e) Prescriptions contain practitioner's DEA number, yes or no? If no, indicate the number with no DEA number.
- (11) Schedule II,IV,V and VI prescriptions include:
- (a) Patient's address, yes or no? If no, indicate the number without patient's address.
  - (b) Practitioner's address, yes or no? If no, indicate the number without the patient's address.
  - (c) Prescription dated, yes or no? If no, indicate the number not dated.
  - (d) Prescriptions contain red "C", yes or no? If no, indicate the number not so marked.\*
  - (e) Prescriptions initialed by physician, yes or not? If no, indicate the number not installed.
  - (f) Prescription refilled more than five times, yes or no? If yes, indicate number refilled more than five times. Provide a listing of 10 prescription numbers to support "yes."\*
  - (g) Prescriptions refilled longer than six-months, yes or no? If yes, indicate the number refilled after six months. Provide a listing of 10 prescription numbers to support "yes."\*6
  - (h) Prescription refilled dated and initialed by the physician on the back of prescription, yes or no? If no, indicate the number not dated and initialed on the back.
  - (i) Prescription for Schedule VI drugs refilled beyond a two-year period, yes or no? If yes, indicate the number refilled beyond two years.7

d. Labeling of Prescriptions (Section54.1-3463 and Board Regulation 18 VAC 110-20-330):

Prescriptions labeled as follows:

- (1) Name and address of dispenser, yes or no? If no, document.
  - (2) Serial number and date of prescription or filling, yes or no? If no, document.
  - (3) Name of prescriber, yes or no? If no, document.
  - (4) Name of patient, yes or no? If no, document.
  - (5) Direction for use, yes or no? If no, document.
  - (6) Trade or generic name and strength, where applicable, yes or no? If no, document.
  - (7) Number of dosage units or millimeters dispensed, yes or no? If no, document
- e. Packaging Standard for Dispensed Prescriptions (Section 54.1-3427 and Board of Pharmacy Regulation 18 VAC 110-20-340):
- (1) Prescriptions, If applicable in a special packaging (safety enclosure), yes or no? If no, document.
  - (2) Sign posted near dispensing area advising that nonspecial packaging may be requested, yes or no? If no, document.
6. Humane Societies and Animal Shelters (Section 54.1-3425 and Board of Pharmacy Regulation 18 VAC 110-20-580):
- a. Permits/licenses (Section 54.1-3430, Code of Virginia):
    - (1) Displayed (Section 54.1-3314 and 54-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
    - (2) Current (Section 54.1-3304, 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
  - b. Facilities under the general supervision of a veterinarian, yes or no? If no, document.
  - c. Person administering the drug been trained by a veterinarian, yes or no? If no, document.
  - d. Person responsible for administering the drug has the only access, yes or no? IF no, document.
  - e. Drug ordered and obtained in injectable form, yes or no? If no, document.
  - f. Invoices and order forms maintained at facilities for two years, yes or no? If no, document.
  - g. Required inventories for Schedule II drugs on-site and current?
    - (1) Biennial Inventory, Yes or no? If no document.
      - (a) Inventory dated, yes or no? If no document
      - (b) Opening and closing of business, yes or no? If no, document
      - (c) Signed by person taking inventory, yes or no? If no, document.
  - h. Complete and accurate records maintained on the administration of the drug as follows:
    - (1) Date of administration, yes or no? If no, document.
    - (2) Species of animal, yes or no? If no. document.
    - (3) Weight of animal, yes or no? If no, document.
    - (4) Amount of drugs administered, yes or no? If no, document.
    - (5) Signature of person administered, yes or no? If no, document.
7. Wholesale Distributor (Section 54.1-3435 and Board of regulation 18 VAC 110-20-630):
- a. Permits/licenses (Section 54.1-3430, Code of Virginia):

- (1) Displayed (Section 54.1-3314 and 54-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the waiting or office area, yes or no? If no, document.
  - (2) Current (Section 54.1-3304, 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document
- b. Standards for Wholesale Distributors :
- (1) Adequate size to facilitate proper operation, yes or no? If no, document
  - (2) Storage area provides adequate lighting, ventilation, temperature and sanitation, yes or no? If no, document.
  - (3) Quarantine area designated for outdated, misbranded drug or damaged prescription drug, yes or no? If no, document.
  - (4) Facility maintained in a clean and orderly manner, yes or no? If no, document.
  - (5) Facility is free from infection by insect or rodents, yes or no? If no, document.
- c. Security System [Board of Pharmacy Regulation 18 VAC 110-20-640]:
- (1) Facilities secured to prevent unauthorized entry, yes or no? If no, document.
  - (2) Access to facility kept to a minimum, yes or no? If no document.
  - (3) Outside perimeter well lighted, yes or no/ IF no, document.
  - (4) Access to Schedule II through V drugs limited to authorized personnel, yes or no? If no, document.
  - (5) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no. document.
  - (6) Devices maintained in operating order, yes or no? If no, document.
  - (7) Device protects the immediate prescription department, yes or no? If no, document.
  - (8) Device has an auxiliary source of power, yes or no? If no, document.
  - (9) Access to alarm system restricted to designated and necessary persons, yes or no? If no, document.
  - (10) Storage area for Schedule II through VI drugs restricted to a limited number of designated employees, yes or no? If no, document.
  - (11) System to protect computerized record tampering, yes or no? If no, document
  - (12) Drugs maintained in proper temperature in accordance with requirements on labels, yes or no? If no, document.
  - (13) Device or manual system maintained to document proper storage of prescription drugs, yes or no? IF no, document.
- d. Drug Inventory and records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulations 18 VAC 110-20-240):
- (1) Inventories and records of Schedule II drugs received, maintained and distributed separate from all other records, yes or no? If no, document.
  - (2) Inventories and records of Schedule II, IV and V drugs received, stored and distributed maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
  - (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
  - (4) Records for Schedule II through V drugs maintained at establishment for two years form date of transaction, yes or no? If no, document.
  - (5) Required inventories for Schedule II through V drug on-site and current?
    - (a) Biennial Inventory, Yes or no? If no document.
      - (i) Inventory dated, yes or no? If no document
      - (ii) Opening and closing of business, yes or no? If no, document.



- (iii) Signed by person taking inventory, yes or no? If no, document
- (b) If applicable: Change of ownership inventory, yes or no, If no, document.
  - (i) Inventory dated, yes or no? If no document
  - (ii) Opening and closing of business, yes or no? If no, document.
  - (iii) Signed by person taking inventory, yes or no? If no, document
- (6) Theft or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration yes or no, If no, document.
- (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.
- (8) Distribution records include:
  - (a) date distributed, yes or no? If no, document.
  - (b) Name and address of person receiving drug, yes or no? If no, document.
  - (c) Name and strength of drug, yes or no? If no, document.
  - (d) Quantity distributed, yes or no? If no, document.
- (9) Records regarding receipt of prescription drugs include:
  - (a) source of drug, yes or no? If no, document.
  - (b) Name and address of seller, yes or no? If no, document.
  - (c) Location from which drug was shipped, yes or no? If no, document.

e. Record Keeping Procedures:

- (1) Written procedures for storage, receipt security, inventory and distribution of prescription drug, yes or no? If no, document
- (2) Written procedures for distribution of oldest stock first, yes or no? If no, document.
- (3) Written procedures for handling recall and withdrawals, yes or no? If no, document.
- (4) Written procedures for handling disposition and storage of prescription drugs, yes or no? If no, document.

8. Manufactures. [Section 54.1-3437, 54.1-3438, 54.1-3439 and 54.1-3441, Code of Virginia and Board of regulation 18 VAC 110-20-630):

a. Permits/licenses (Section 54.1-3430, Code of Virginia):

- (1) Displayed (Section 54.1-3314 and 54-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
- (2) Current (Section 54.1-3304, 54.1-3441, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.

b. Manufacturing of Drugs Supervised by Pharmacist (Section 54.1-3438, Code of Virginia):  
Drugs manufactured, packaged, repackaged, relabeled, or prepared under the personal or immediate supervision of a pharmacist or other such person approved by the Board, yes or no? If no, document.

c. Security System [Board of Pharmacy Regulation 18 VAC 110-20-640]:

- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yea or no? If no. document.
- (2) Devices maintained in operating order, yes or no? If no, document.
- (3) Device protects the immediate prescription department, yes or no? If no, document.
- (4) Device has an auxiliary source of power, yes or no? If no, document.

d. Drug Inventory and Records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulations 18 VAC 110-20-240):

- (1) Inventories and records of Schedule II drugs received, distributed, and maintained separate from all other records, yes or no? If no, document.
- (2) Inventories and records of Schedule II, IV and V drugs received, stored and distributed maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
- (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
- (4) Records for Schedule II through V drugs maintained at establishment for two years form date of transaction, yes or no? If no, document.
- (5) Required inventories for Schedule II through V drug on-site and current?
  - (a) Biennial Inventory, Yes or no? If no document.
    - (i) Inventory dated, yes or no? If no document
    - (ii) Opening and closing of business, yes or no? If no, document.
    - (iii) Signed by person taking inventory, yes or no? If no, document
  - (c) If applicable: Change of ownership inventory, yes or no, If no, document.
    - (i) Inventory dated, yes or no? If no document
    - (ii) Opening and closing of business, yes or no? If no, document.
    - (iii) Signed by person taking inventory, yes or no? If no, document
- (6) Theft or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration yes or no, If no, document.
- (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.

e. Good Manufacturing Practice (GMPs) [Board of Pharmacy Regulation 18 VAC 110-20-660]:

- (1) Building and Facilities:
  - (a) Building contains defined areas to prevent contamination or mix-up as follows:
    - (i) Quarantine area for the receipt, storage, and withholding from use of components, pending testing before release for manufacturing, yes or no? If no, document.
    - (ii) Storage of rejected components, yes or no? If no, document.
    - (iii) Storage of released components, drug containers, yes or no? If no, document.
    - (iv) Packaging and labeling operation, yes or no? If no, document.
    - (v) Control and laboratory operation, yes or no/ If no, document.
    - (vi) Separate area for manufacturing, processing and packaging penicillin products, yes or no? If no, document.
  - (b) Lighting [Board of Pharmacy Regulation 18 VAC 110-20-660]: The inspector will measure the manufacturer's candlepower with a light meter and record the candlepower on the inspection form.
  - (c) Ventilation [Board of Pharmacy Regulation 18 VAC 110-20-660]: the inspector will describe the manufacture's ventilation system on the inspection form.
  - (d) Washing and Toilet Facilities include:
    - (i) Hot and cold running water, yes or no? If no, document.
    - (ii) Soap or detergent, yes or no? If no, document.
    - (iii) Air dryers or single-service towels, yes or no? If no, document.
    - (iv) Toilet facilities, yes or no? If no, document.

- (e) Sanitary Conditions [Board of Pharmacy Regulation 18 VAC 110-20-660]: If the building is unclean or not free of filth that could contaminate drug products, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
    - (i) Written procedure maintained describing in detail the cleaning schedule and method, yes or no? If no, document.
    - (ii) Written procedures maintained for the use of suitable insecticides, cleaning and sanitizing agents, yes or no? If no, document.
  - (f) Equipment [Board of Pharmacy Regulation 18 VAC 110-20-660]: If the building is unclean or not free of filth that could contaminate drug products, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
    - (i) Written procedure maintained describing in detail the cleaning schedule and method, yes or no? If no, document.
    - (ii) records maintained on cleaning, sanitizing, and inspecting the equipment, yes or no? If no, document.
- (2) Control of Components, Drug products, Containers and Closures:
- (a) Written procedures describing the receiving, identifying, storing, handling, sampling, test, and approving or rejecting components, yes or no? If no, document.
  - (b) Component, drug product containers, and closures stored under quarantine until tested or examined and released, yes or no? If no, document.
  - (c) Records maintained of the testing of each component prior to the use in the manufacturing process, yes or no? If no, document.
  - (d) Rejected components identified and controlled under a quarantine system to prevent contamination in manufacturing or processing operations, yes or no? If no, document.
- (3) Production and Process controls:
- (a) Written procedures designed to assure that the drug products have the identity, strength, quality, and purity they purport or represent to possess, yes or no? If no, document.
  - (b) The procedures include:
    - (i) Charge-in of component, yes or no? If no, document.
    - (ii) Calculation of yield, yes or no? If no, document.
    - (iii) Equipment identification, yes or no/ If no, document.
    - (iv) Sampling and listing of in-process materials and drug products, yes or no? If no, document.
    - (v) Time limitations on production, yes or no? If no, document.
    - (vi) Control microbiological contamination, yes or no? If no, document.
    - (vii) Reprocessing, batching, yes or no? If no, document.
- (4) Packaging and Labeling Control :
- (a) Written procedures describing the receiving, identifying, storing, handling, sampling, testing, and approving, or rejecting labels, yes or no? If no, document.
  - (b) Labeling issuance:

- (i) Procedures utilized to reconcile the quantities issued, used and returned, yes or no? If no, document.
    - (ii) Excess labeling bearing lot or control number destroyed, yes or no? If no, document.
    - (iii) Procedure written describing in detailed the control procedure for the issuance of labeling.
  - (c) Packaging and labeling operations; written procedures to assure that correct labels, labeling, and packaging are used for drug products, yes or no? If no, document.
  - (d) Drug product inspection:
    - (i) Packaged and labeled products examined during finishing operations to assure that container and package in lot have correct label, yes or no? If no, document.
    - (ii) Representative sample of unit collected at completion of finishing operation and visually examined for correct labeling, yes or no? If no, document.
    - (iii) Results of examination recorded in batch production or control records, yes or no? If no, document.
- (5) Laboratory Controls:
- (a) Written procedures for sampling and testing plans, yes or no? If no, document.
  - (b) Procedures include:
    - (i) Appropriate determination for conformance to final specification for identity and strength of each active ingredient, yes or no? If no, document.
    - (ii) Appropriate testing, as necessary, of each batch of drug product for microorganisms, yes or no? If no, document.
  - (c) Stability testing: a written testing program designed to assess the stability characteristics of drug products, yes or no? If no, document.
  - (d) Reserve samples:
    - (i) Appropriate identified reserve sample representative of each lot or batch of drugs retained, yes or no? If no, document.
    - (ii) Reserve sample retained for one year after expiration date of the last lot of drug product, yes or no? If no, document.
    - (iii) Reserve sample stored in same container in which the product is marketed, yes or no? If no, document.
- (6) Records and Reports:
- (a) Equipment cleaning and uses log: maintain a written record of equipment cleaning and use log, yes or no? If no, document.
  - (b) Master production and control records maintained for each batch of drug product produced, yes or no? If no, document.
    - (i) An accurate reproduction of the appropriate master production or control record, checked, dated, and signed, yes or no? If no, document.

- (ii) Documentation that each significant step in the manufacturing, processing, packing, or holding of the batch was accomplished, yes or no? If no, document.
- (i) Name and strength of drug product, yes or no? If no, document.
- (ii) Description of dosage form, yes or no? If no, document.
- (iii) Name and address of consignee, date, quantity shipped, and lot or control number of drug product, yes or no? If no document.

(c) Complaint files maintained which include:

- (i) Written procedures for handling written and oral complaints regarding a drug product, yes or no? If no, document.
- (ii) Written records of each complaint maintained in a file designated for drug product complaints, yes or no? If no, document.
- (iii) Complaint records maintained for one year after the expiration date of the product or for one year after the expiration date the complaint was received, yes or no? If no, document.

9. Warehouser (Section 54.1-3435.4, 54.1-3435.5, and Board of regulation 18 VAC 110-20-630):

a. Permits/licenses (Section 54.1-3430, Code of Virginia):

- (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
- (2) Current (Section 54.1-3430, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.

b. Restricted Access for Schedule II through V Drugs (Board of Pharmacy Regulation 18 VAC 110-20-640):

- (1) Access restricted where Schedule II through V drugs are stored to a limited number of designated and necessary persons, yes or no? If no, document.
- (2) Reasonable measures taken to prevent persons from pilfering drugs from the restricted areas, yes or no? If no, document.

c. Security System [Board of Pharmacy Regulation 18 VAC 110-20-640]:

- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each storage area, yea or no? If no, document.
- (2) Devices maintained in operating order, yes or no? If no, document.
- (3) Device protects the immediate drug storage area, yes or no? If no, document.
- (4) Device has an auxiliary source of power, yes or no? If no, document.

d. Drug Inventory and records (Section 54.3404, 54.1-3411, 54.1-3412, and Board of Pharmacy Regulations 18 VAC 110-20-240):

- (1) Inventories and records of Schedule II drugs received, maintained and distributed separate from all other records, yes or no? If no, document.
- (2) Inventories and records of Schedule II, IV and V drugs received, stored and distributed maintained separately or with records of Schedule VI drugs, yes or no? If no, document.
- (3) Schedule II through V records maintained at same location as the stock of drugs to which the records pertain, yes or no? If no, document.
- (4) Records for Schedule II through V drugs maintained at establishment for two years form date of transaction, yes or no? If no, document.

- (5) Required inventories for Schedule II through V drug on-site and current?
  - (a) Biennial Inventory, Yes or no? If no document.
    - (i) Inventory dated, yes or no? If no document
    - (ii) Opening and closing of business, yes or no? If no, document.
    - (iii) Signed by person taking inventory, yes or no? If no, document
  - (b) If applicable: Change of ownership inventory, yes or no, If no, document.
    - (i) Inventory dated, yes or no? If no document
    - (ii) Opening and closing of business, yes or no? If no, document.
    - (iii) Signed by person taking inventory, yes or no? If no, document
- (6) Theft or losses of Schedule II through V drugs reported immediately to the Board of Pharmacy and the Drug Enforcement Administration yes or no, If no, document.
- (7) Receipt of Schedule II through V drugs dated with actual date of receipt, yes or no? If no, document.

10. Medical Equipment Suppliers (Section 54.1-3435.2 and 54.1-3435.3 and Board of Regulation 18 VAC 110-20-630):

a. Permits/licenses (Section 54.1-3430, Code of Virginia):

- (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
- (2) Current (Section 54.1-3430): All permits, licenses, and certificates current, yes or no? If no, document.

b. Physical Standards:

- (1) Facility maintained in a clean and orderly manner, yes or no? If no, document.
- (2) Storage area provides adequate lighting, ventilation, and temperature, yes or no? If no, document.

c. Security :

- (1) Facility secured to prevent unauthorized entry, yes or no? If no, document.
- (2) Access to prescription drugs limited to authorized personnel, yes or no? If no, document.

d. Records:

- (1) Order signed by practitioner on file, yes or no? If no, document.
- (2) Signed order maintained on premise for two years, yes or no? If no, document.
- (3) Required dispensing records maintained for two years, yes or no? If no, document.
- (4) Required records include:
  - (a) Name and address of patient, yes or no? If no, document.
  - (b) Item dispensed and quantity, yes or no? If no, document.
  - (c) Date of dispensing, yes or no? If no, document.

11. Practitioners Licensed to Sell Control Substances: [Board of Pharmacy Regulation 18 VAC 110-30-10]:

- a. Permits/licenses (Section 54.1-3430, Code of Virginia):
- (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
  - (2) Current (Section 54.1-3430): All permits, licenses, and certificates current, yes or no? If no, document.
- b. Physical Standards for Controlled Substances Selling and Storage Area (Board of Pharmacy Regulation 18 VAC 110-30-90):
- (1) Controlled Substances Selling and Storage Area [Board of Pharmacy Regulation 18 VAC 110-30-90.1]: Is the area designated as the controlled substances selling and storage area at least 60 square feet, yes or no? If no, document.
  - (2) Controlled Substances Maintained Separately [Board of Pharmacy Regulations 18 VAC 110-30-90.3]: Controlled substances for sale maintained separately from other controlled substances maintained for other purposes, yes or no? If no, document.
  - (3) Counter Space: Board of Pharmacy Regulation 18 VAC 110-30-90.2]: Counter work space located in storage area, yes or no? If no, document. If the work counter space in the area is unclean and not orderly, the inspector will describe the conditions in the inspection report and will take photographs to substantiate the exact nature of the unsanitary conditions
  - (4) Sink: [Board of Pharmacy Regulation 18 VAC 110-30-90.5]: Is there a sink with hot and cold running water within the immediate selling and storage area, yes or no? If no, document.
  - (5) Lighting and Ventilation: [Board of Pharmacy Regulation 18 VAC 110-30-90.6]: Entire area well lighted and ventilated; proper storage temperature maintained to meet specifications for controlled substances, yes or no? If no, document.
- c. Access to Selling Area: (Board of Pharmacy Regulation 18 VAC 110-30-100): Is access to stock rooms, rest room, and other areas other than an office for the licensee through the selling and storage, yes or no? If no, document.
- d. Minimum Equipment: (Board of Pharmacy Regulation 18 VAC 110-30-110):
- (1) Current copy of the U.S.P. Dispensing Information, yes or no? If no, document.
  - (2) Refrigerators with monitoring thermometer in selling area if controlled substances require refrigeration, yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board regulations, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary, yes or no? If no, document.
  - (5) Laminar Flow hood, if sterile product(s) one to be prepared, yes or no? If no, document
  - (6) Prescription balance and weights, if engaging in extemporaneous compounding, yes or no? If no, document.
- e. Safeguard Against Diversion of Controlled Substances: (Board of Pharmacy Regulation 18 VAC 110-30-120):
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in the controlled substances selling and storage area, yes or no? If no, document.
  - (2) Devices maintained in operating order, yes or no? If no, document.
  - (3) Device fully protect the immediate controlled substance selling and storage area and capable of detecting breaking in the area when area is closed, yes or no? If no, document.
  - (4) Alarm system has an auxiliary source of power, yes or no? If no, document.

- (5) Alarm system activated and operated separately from any other alarm system in the area or business in which the controlled substance selling and storage area is located, yes or no? If no, document.
- (6) Alarm system controlled only by the licensee, yes or no? If no, document.

f. Selling Area Enclosures (Board of Pharmacy Regulation 18 VAC 110-30-130):

- (1) Enclosure constructed in such a manner that it protects the controlled substance stock from unauthorized entry whether or not a licensee is on duty, yes or no? If no, document.
- (2) Enclosure of sufficient height or to prevent anyone from reaching over to gain access to the controlled substances, yes or no? If no, document.
- (3) Entrance to enclosure area have a door which extends from the floor to and which is at least as high as the adjacent counter partitions, yes or no? If no, document?
- (4) Doors to area have adequate locking devices, yes or no? If no, document.
- (5) Only licensees in possession of the alarm access code and any keys to the locking device on the floor to such enclosure, yes or no? If no, document.
- (6) If there is an emergency key and alarm access code to the enclosure, is it maintained in a sealed envelope, signed by the licensee, and place in a safe or other secured place, yes or no? If no, document

g. Prescriptions Awaiting Delivery: (Board of Pharmacy Regulation 18 VAC 110-30-140):  
Prescriptions awaiting delivery to patients stored in a secured place outside of the selling area and access restricted by the licensee to designated assistants, yes or no? If no, document.

h. Expired Controlled Substances: Security (Board of Pharmacy Regulation 18 VAC 110-30-150): Expired drugs separated from the stock used for selling and maintained in a designated area, yes or no? If no, document.

i. Sign and Written Prescription Requirement (Board of Pharmacy Regulation 18 VAC 110-30-170):

- (1) Sign posted in a public area advising public that controlled substances may be obtained from him or from a pharmacy, yes or no? If no, document.
- (2) If the patients purchase controlled substances from licensee, prescription signed by patient, filed chronologically and maintained for two years, yes or no? If no, document.

j. Manner of Maintaining Records, Prescriptions, Inventory Records for Licensees Selling Controlled Substances Section 54.1-3404, 54.1-3411, Code of Virginia and Board of Pharmacy Regulation 18 VAC 110-30-180 and 110-30-190):

- (1) Required Inventory for Schedule II through V controlled substances on site and current, yes or no? If no, document.
  - a. Biennial Inventory, yes or no? If no, document.
    - (i) Inventory dated, yes or no? If no document
    - (ii) Opening and closing of business, yes or no? If no, document.
    - (iii) Signed by person taking inventory, yes or no? If no, document
- (2) Inventories and records of controlled substances listed in Schedule II maintained separate from all other records, yes or no? If no, document.
- (3) Inventories and records of controlled substances listed in Schedule III, IV and V maintained separately or with records of Schedule VI drugs, yes or no? If no, document.



- (4) Records of Schedule II through V controlled substances maintained at the same location as the stock of drugs to which the records pertain, yes or no? If no, document.
- (5) Records of Schedule II through V controlled substances maintained by the licensee for two years from the date of transaction, yes or no? If no, document
- (6) Theft or losses of Schedule II through V controlled substance reported immediately to the Board of Pharmacy and the Drug Enforcement Administration yes or no, If no, document.
- (7) Receipt of Schedule II through V controlled substances dated with the actual date of receipt, yes or no? If no, document.
- (8) Records of selling Schedule II controlled substances maintained separate from other records, and in a chronological order, yes or no? If no, document.
- (9) Records of selling Schedule II controlled substances includes:
  - (a) Selling date, yes or no? If no, document.
  - (b) A number identifying the sale, yes or no? If no, document.
  - (c) Name and address of patient, yes or no? If no, document.
  - (d) Name and strength of control substances and quantity sold, yes or no? If no, document.
- (10) Records for selling Schedule II through V controlled substances maintained in a separate file, yes or no? If no, are they filled in such a form that they are readily retrievable (red "C" placed on record entry line from selling records for Schedule VI controlled substances) yes or no? If no, indicate the number of records not maintained according to regulations.
- (11) Records of selling Schedule II controlled substances includes:
  - (a) Selling date, yes or no? If no, document.
  - (b) A number identifying the sale, yes or no? If no, document.
  - (c) Name and address of patient, yes or no? If no, document.
  - (d) Name and strength of control substances and quantity sold, yes or no? If no, document.

k. Automated Data Processing Records of Sale (Board of Pharmacy Regulation 18 VAC 110-30-200):

- (1) Computerized system provide retrieval via CRT display or printout of the sale of controlled substance during the past two years in chronological order and include all information required by method, yes or no? If no, document.
- (2) If the system provides a printout of each day selling, is the printout verified, dated and signed by the licensee who sold the controlled substances, yes or no? If no, document.
- (3) If the system does not provide a daily printout, does the licensee maintain a bond log book or separate file, verified, dated and signed by the licensee as describe in (2) above, yes or no? If no, document.

l. Repackaging of Controlled Substances: Records Required (Board of Pharmacy Regulation 18 VAC 110-30-210):

- (1) Control records maintained for one year or until the expiration date of drugs, yes or no? If no, document.
- (2) Records contained:
  - (a) Name of controlled substance(s) repackaged, yes or no? If no, document.
  - (b) Strength of controlled substance(s) repackaged, yes or no? If no, document
  - (c) Quantity repackaged, yes or no? If no, document.
  - (d) Initials of supervising licensee, yes or no? IF no, document.

- (e) Manufacturer's or distributor's name, yes or no? If no, document.
- (f) Control number or assigned number, yes or no? If no, document.
- (g) Expiration date, yes or no? If no, document.

(3) Repackaged drug labeled as follows:

- (a) Name and strength of controlled substances, yes or no? If no, document
- (b) Manufacturer's or distributor's name and control number or assigned number, yes or no? If no, document.
- (c) Proper expiration date, yes or no? If no, document.

m. Labeling of Prescription as to Content and Quantity (Section 54.1-3463 and Board of Pharmacy Regulation 18 VAC 110-30-210):

- (1) Name and address of practitioner, yes or no? If no, document.
- (2) Name of patient, yes or no? If no, document.
- (3) Date of prescription, yes or no? If no, document.
- (4) Controlled substance name and strength, yes or no? If no, document.
- (5) Number of dosage units, or if liquid, the number of millimeters dispensed, yes or no? If no, document.

n. Packaging Standards for Controlled Substance (Section 54.1-3427 and Board of Pharmacy Regulation 18 VAC 110-30-230):

- (1) Controlled substance(s) if applicable, sold in special packaging (safety enclosure), yes or no? If no, document.
- (2) Sign post near selling area advising that non-special packaging may be requested, yes or no? If no, document.

12. Persons or entities authorized or required to obtain a controlled substance registration[Board Regulation 18 VAC 110-20-690]:

a. Permits/Licenses (Sections 54.1-3314 and 54-3430, Code of Virginia):

- (1) Displayed (Sections 54.1-3314 and 54.1-3430): Each permit, license, and/or certificate must be posted for public view in a common area. A common area would be the waiting area, yes or no? If no, document.
- (2) Current (Sections 54.1-3314, 54-3430 and 54.1-3434): All permits, licenses, and certificates current, yes or no? If no, document.

b. Access to controlled substances[Board of Pharmacy Regulation 110-20-700.C]:

- (1) access to controlled substances restricted to supervising practitioner, person authorized by supervising practitioner, who are authorized by law to administer drugs, yes or no? If no, document.

c. Requirements for storage and security for controlled substance registrants[Board of Pharmacy Regulation 18 VAC 110-20-710]:

- (1) Drugs stored under USP-NF or manufacturer specifications, yes or no? If no, document.
- (2) Expired drugs maintained from separately from stock used for administration and locked, yes or no? If no, document.

- (3) Drugs maintained in a lockable cabinet, cart, device or other area which is locked when not in use, yes or no? If no, document.
- (4) Keys or access code restricted to supervising practitioners or person designated access, yes or no? If no, document.
- (5) If facility not staffed 24 hours a day, drugs shall be stored in a fixed and secure room, cabinet or area which a security devise meeting the following conditions:
  - (a) A sound, microwave, or photoelectric device for detecting a breaking installed in each area where prescription drugs are stored, yes or no? If no, document.
  - (b) Device maintained in operating order, yes or no? If no, document.
  - (c) Device protects all areas where prescription drugs are stored, yes or no? If no, document.
  - (d) Device has an auxiliary source of power, yes or no? If no, document.
  - (e) Alarm system controlled only by the designated and necessary person and activated when drug storage areas are closed for business, yes or no? If no, document.

d. Requirements for record keeping [Board of Pharmacy Regulation 18 VAC 110-20-720]:

- (1) Inventory and records of Schedule II drugs maintained separate from all other records, yes or no? If no, document.
- (2) All records maintained at same location listed on the controlled substance registration, yes or no? If no, document.
- (3) Required inventories for Schedule II through V drugs on-site and current?
  - (a) Biennial inventory, yes or no? If no, document.
    - (i) inventory dated, yes or no? If no, document.
    - (ii) opening or closing of business, yes or no? If no, document.
    - (iii) signed by a person taking inventory, yes or no? If no, document.
- (4) If automated system used to maintain records, is it capable to display or print out listing of drugs administered for 2 years, yes or no? If no, document.

B. New Establishment Inspections: The inspector will inspect only those items required prior to opening. The same measures used to inspect in Section VI-A (Routine Inspections) will be used to determine compliance in new establishment inspections. When conducting a new establishment inspection, the inspector will determine the following:

1. Community Pharmacies (Retail):

a. Physical Standards for Pharmacies (Board of Pharmacy Regulation 18 VAC 110-20-150):

- (1) Space requirements [Board of Pharmacy Regulation 18 VAC 110-20-150 (A)]: Is the storage, compounding, and preparation area at least 240 square feet, yes or no? If no, document. The inspector will measure and record the size of the prescription room on the inspection form.

- (2) Access to Dispensing Area [Board of Pharmacy Regulation 18 VAC 110-20-150 (B)]: Is access to stock room, rest rooms, and other areas through the dispensing area, yes or no? If no, document.
  - (3) Temperature [Board of Pharmacy Regulation 18 VAC 110-20-150 (D)]: The pharmacy shall maintain a temperature between 59 and 86 degrees Fahrenheit and shall be well lighted and ventilated. The inspector will measure with a thermometer and record it on the inspection form.
  - (4) Counter Space [Board of Pharmacy Regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping, yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (5) Sink [Board of Pharmacy 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
  - (6) Refrigerator [Board of Pharmacy Regulation 18 VAC 110-20-150 (G)]: Refrigeration facilities with monitoring thermometer maintained within prescription department, yes or no? If no, document.
- b. Sanitary Conditions (Board of Pharmacy Regulation 18 VAC 150-20-160)
- (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (2) Trash disposal facilities and receptacles, yes or no? If no, document.
- c. Required Minimum Equipment (Board of Pharmacy Regulation 18 VAC 110-20-170):
- (1) Current Dispensing Information reference source, yes or no? If no, document.
  - (2) Prescription Balance sensitive to 15 mg weights or an electric scale yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board Regulation, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary, yes or no? If no, document.
  - (5) Other equipment, supplies and references consistent with the scope of practice yes or no? If no, document.
- d. Security System [Section 54.1-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each prescription department, yes or no? If no, document.

- (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device protects the prescription department, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
  - (5) Alarm system controlled only by the pharmacist(s) and activated when pharmacy is closed for business, yes or no? If no, document.
- e. Prescription Department Enclosures [Board of Pharmacy Regulation 18 VAC 110-20-190]:
- (1) Enclosure constructed in such a manner that it protects the controlled drug stock from unauthorized entry whether or not a pharmacist is on duty. The inspector will describe the enclosure on the inspection form.
  - (2) Enclosure of sufficient height to prevent from reaching over and gaining access to the drugs. The inspector will measure the height of enclosure and record on the inspection form.
  - (3) Entrances to enclosed area have a door with no more than a six-inch gap from the floor and which is at least as high as the adjacent counter, yes or no? If no, document.
  - (4) Doors to area have adequate locking devices yes or no? If no, document. The inspector will describe the type of locking device on the inspection form.
  - (5) Only pharmacist(s) in possession of any keys to the locking device on door to enclosure, yes or no? If no, document.
  - (6) If there is an emergency key or access code to the enclosure, is it maintained in a sealed envelope, signed by a pharmacist, and placed in safe or other secured place, yes or no? If no, document.

2. Hospital Pharmacies

- a. Physical Standards for Pharmacies(Board of Pharmacy Regulation 18 VAC 110-20-150):
- (1) Space Requirement [Board of Pharmacy Regulation 18 VAC 110-20-150 (A)]: Is the storage, compounding, and preparation area at least 240 square feet, yes or no? If no, document. The inspector will measure and record the size of the prescription room on the inspection form.
  - (2) Access to Dispensing Area[Board of Pharmacy Regulation 18 VAC 110-20-150 (B)]: Is access to stock room, rest rooms, and other areas through the dispensing area, yes or no? If no, document.
  - (3) Temperature[Board of Pharmacy Regulation 18 VAC 110-20-150 (D)]: The pharmacy shall maintain a temperature between 59 degrees and 86 degrees Fahrenheit and shall be well lighted and ventilated. The inspector will measure the temperature with a thermometer and record on the inspection form.

- (4) Counter Space[Board of Pharmacy Regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping, yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (5) Sink [Board of Pharmacy Regulation 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
  - (6) Refrigerator [Board of Pharmacy Regulation 18 VAC 110-20-150 (G)]: Refrigeration facilities with monitoring thermometer maintained within prescription department.
- b. Sanitary Conditions (Board of Pharmacy Regulation 18 VAC 110-20-160):
- (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
  - (2) Trash disposal facilities and receptacles, yes or no? If no, document.
- c. Required Minimum Equipment (Board of Pharmacy Regulation 18 VAC 110-20-170):
- (1) Current Dispensing Information reference source, yes or no? If no, document.
  - (2) Prescription Balance sensitive to 15 mg. weight or an electronic scale, yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board regulations, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary, yes or no? If no, document.
  - (5) Other equipment, supplies and references consistent with the scope of practice, yes or no? If no, document.
- d. Security System[Section 54.1-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each dispensing and drug storage area, yes or no? If no, document.
  - (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate storage and dispensing area, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.

- (5) Alarm system controlled only by the pharmacist(s) and nursing supervisor and activated when pharmacy is closed for business, yes or no? If no, document.
- e. Dispensing Area Enclosures[Board of Pharmacy Regulation 18 VAC 110-20-190]:
- (1) Enclosure constructed in such a manner that it protects the controlled drug stock from unauthorized entry whether or not a pharmacist is on duty. The inspector will describe the enclosure on the inspection form.
  - (2) Enclosure of sufficient height to prevent from reaching over and gaining access to the drugs. The inspector will measure the height of enclosure and record on the inspection form
  - (3) Entrances to enclosed area have a door with no more than a six inch gap from the floor which is at least as high as the adjacent counter, yes or no? If no, document.
  - (4) Doors to area have adequate locking devices, yes or no? If no, document. The inspector will describe the type of locking device on the inspection form.
  - (5) Only pharmacist(s) in possession of any keys to the locking device on door to enclosure yes or no? If no, document.
  - (6) If there is an emergency key or access code to the enclosure, is it maintained in a sealed envelope, signed by a pharmacist, and placed in a safe or other secured place, yes or no? If no, document.
- f. After-hours Access of the Pharmacy(Board of Pharmacy Regulation 18 VAC 110-20-450):
- (1) Supervisory nurse has access to pharmacy, yes or no? If no, indicate title of person who has access, if applicable.
3. Nuclear Pharmacies(Board of Pharmacy Regulation 18 VAC 110-20-220)
- a. Physical Standards for Pharmacies (Board of Pharmacy Regulation 18 VAC 110-20-150):
- (1) Space Requirements [Board of Pharmacy Regulation 18 VAC 110-20-150 (A)]: Is the storage, compounding, and preparation area at least 240 square feet, yes or no? If no, document. The inspector will measure and record the size of the prescription room on the inspection form.
  - (2) Access to Dispensing Are[Board of Pharmacy Regulation 18 VAC 110-20-150 (B)]: Is access to stock rooms, rest rooms, and other areas through the dispensing area, yes or no? If no, document.
  - (3) Temperature [Board of Pharmacy Regulation 18 VAC 110-20-150 (D)]: The pharmacy shall maintain a temperature between 59 degrees and 86 degrees Fahrenheit and shall be well lighted and ventilated. The inspector will measure the temperature with a thermometer and record on the inspection form.

- (4) Counter Space[Board of Pharmacy Regulation 18 VAC 110-20-150 (E)]: Counter work space used only for compounding and dispensing drugs and necessary record keeping yes or no? If no, document. If the work counter space and equipment in the dispensing area is unclean and not orderly, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary condition.
  - (5) Sink[Board of Pharmacy Regulation 18 VAC 110-20-150 (F)]: Is there a sink with hot and cold running water within the immediate compounding and dispensing area, yes or no? If no, document.
- b. Sanitary Conditions (Board of Pharmacy Regulation 18 VAC 110-20-160):
- (1) If the pharmacy is unclean or not free of filth that could endanger the health of patients, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
- c. Security System[Section 54.1-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each dispensing and drug storage area, yes or no? If no, document.
  - (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate storage and dispensing area, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
  - (5) Alarm system controlled only by the pharmacist(s) and nursing supervisor and activated when pharmacy is closed for business, yes or no? If no, document.
4. Special or Limited-Use Pharmacy Permits(Board of Pharmacy Regulation 18 VAC 110-20-120):
- a. The inspection items of a special or limited-use pharmacy will be determined b the scope of practice.
  - b. The inspector will inspect the appropriate areas as outlined in Section VI(A)(1) of this plan.
5. Permitted Physicians Licensed to Dispense Drugs(Section 54.1-3304 and Board of Pharmacy Regulation 18 VAC 110-20-410):
- a. Permits/Licenses (Section 54.1-3304, Code of Virginia):
    - (1) Displayed (Section 54.1-3304): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.



- (2) Current (Sections 54.1-3304, 54.1-3425, and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
- b. Security System[Section 54.1-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each dispensing and drug storage area, yes or no? If no, document.
  - (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate storage and dispensing area, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
  - (5) Only the physician in possession of keys and access code to the drug storage area, yes or no? If no, document.
6. Humane Societies and Animal Shelters (Section 54.1-3425 and Board of Pharmacy Regulation 18 VAC 110-20-580):
- a. Permits/Licenses(Section 54.1-3430, Code of Virginia):
    - (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
    - (2) Current (Sections 54.1-3430 and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
  - b. Facility under the general supervision of a veterinarian, yes or no? If no, document.
  - c. Person administering the drug been trained by a veterinarian, yes or no? If no, document.
  - d. Person responsible for administering the drug have the only access, yes or no? If no, document.
7. Wholesale Distributor (Sections 54.1-3435 and 54.1-3436 and Board Regulation 18 VAC 110-20-630):
- a. Permits/Licenses(Section 54.1-3430, Code of Virginia):
    - (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
    - (2) Current (Sections 54.1-3430, 54.1-3441 and 54.1-3423): All permits, licenses, and certificates current, yes or no? If no, document.
  - b. Standards for Wholesale Distributors:
    - (1) Adequate size to facilitate proper operations, yes or no? If no, document.

- (2) Storage area provide adequate lighting, ventilation, temperature and sanitation, yes or no? If no, document.
  - (3) Quarantine area designated for outdated, misbranded or damaged prescription drugs, yes or no? If no, document.
  - (4) Facility maintained in a clean and orderly manner, yes or no? If no, document.
  - (5) Facility free from infestation by insects and rodents, yes or no? If no, document.
- c. Security System [Board of Pharmacy Regulation 18 VAC 110-20-640]:
- (1) Facility secured to prevent unauthorized entry, yes or no? If no, document.
  - (2) Access to facility kept to a minimum, yes or no? If no, document.
  - (3) Outside perimeter well lighted, yes or no? If no, document.
  - (4) Access to Schedule II through VI drugs limited to authorized personnel, yes or no? If no, document.
  - (5) A sound, microwave, or photoelectric device for detecting a breaking installed in each drug storage area, yes or no? If no, document.
  - (6) Device maintained in operating order, yes or no? If no, document.
  - (7) Device protects the immediate drug storage area, yes or no? If no, document.
  - (8) Device has an auxiliary source of power yes or no? If no, document.
  - (9) Storage area for Schedule II through VI drugs restricted to a limited number of designated employees, yes or no? If no, document.
  - (10) System to protect computerized record tampering, yes or no? If no, document.
  - (11) Drugs maintained at proper temperature in accordance with requirements on labels, yes or no? If no, document.
  - (12) Device or manual system maintained to document proper storage of prescription drugs, yes or no? If no, document.
8. Manufacturers (Section 54.1-3437, 54.1-3438, and 54.1-3439, Code of Virginia and Board of Pharmacy Regulations 18 VAC 110-20-630):
- a. Permits/Licenses(Section 54.1-3430, Code of Virginia):
    - (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the hospital pharmacy reception area, yes or no? If no, document.
    - (2) Current (Sections 54.1-3430, 54.1-3441 and 54.1-3423): All permits,

licenses, and certificates current, yes or no? If no, document.

- b. Manufacturing of Drugs Supervised by Pharmacist (Section 54.1-3838, Code of Virginia):
  - (1) Drugs manufactured, packaged, repackaged, relabeled, or prepared under the personal or immediate supervision of a pharmacist or other such person approved by the Board, yes or no? If no, document.
- c. Security System[Section 54.1-3434 and Board of Pharmacy Regulation 18 VAC 110-20-180]:
  - (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each dispensing and drug storage area, yes or no? If no, document.
  - (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device protects the immediate storage and dispensing area, yes or no? If no, document.
  - (4) Device has an auxiliary source of power, yes or no? If no, document.
- d. Good Manufacturing Practice (GMPs) [Board of Pharmacy Regulation 18 VAC 110-20-660]:
  - (1) Building and Facilities:
    - (a) Building contains defined areas to prevent contamination or mix-up as follows:
      - (i) quarantine area for the receipt, storage, and withholding from use of components, pending testing before release for manufacturing, yes or no? If no, document.
      - (ii) storage of rejected components, yes or no? If no, document.
      - (iii) storage of released components, drug containers, yes or no? If no, document.
      - (iv) packaging and labeling operation, yes or no? If no, document.
      - (v) control and laboratory operation, yes or no? If no, document.
      - (vi) separate area for manufacturing, processing and packaging penicillin products, yes or no? If no, document.
    - (b) Lighting [Board of Pharmacy Regulation 18 VAC 110-20-660]: The inspector will measure the manufacturer's candlepower with a light meter and record the candlepower on the inspection form.
    - (c) Ventilation [Board of Pharmacy Regulation 18 VAC 110-20-660]: The inspector will describe the manufacture's ventilation system on the inspection form.
    - (d) Washing and Toilet Facilities include:
      - (i) hot and cold running water, yes or no? If no, document.
      - (ii) soap or detergent, yes or no? If no, document.
      - (iii) air dryers or single-service towels, yes or no? If no, document.
      - (iv) Toilet facilities, yes or no? If no, document.

- (e) Sanitary Conditions [Board of Pharmacy Regulation 18 VAC 110-20-660]: If the building is unclean or not free of filth that could contaminate drug products, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
    - (i) written procedure maintained describing in detail the cleaning schedule and method, yes or no? If no, document.
    - (ii) written procedures maintained for the use of suitable insecticides, cleaning and sanitizing agents, yes or no? If no, document.
  - (f) Equipment [Board of Pharmacy Regulation 18 VAC 110-20-660]: If the building is unclean or not free of filth that could contaminate drug products, the inspector will describe the conditions on the inspection form and take photographs to substantiate the exact nature of the unsanitary conditions.
    - (i) written procedure maintained describing in detail the cleaning schedule and method, yes or no? If no, document.
    - (ii) records maintained on cleaning, sanitizing, and inspecting the equipment, yes or no? If no, document.
- (2) Control Components, Drug Products, Containers, and Closures:
- (a) Written procedures describing the receiving, identifying, storing, handling, sampling, testing, and approving or rejecting components, yes or no? If no, document.
- (3) Production and Process Controls:
- (a) Written procedures describing the receiving, identifying, storing, handling, sampling, testing, and approving or rejecting components, yes or no? If no, document.
  - (b) The procedures include:
    - (i) charge-in of components, yes or no? If no, document.
    - (ii) calculation of yield, yes or no? If no, document.
    - (iii) equipment identification, yes or no? If no, document.
    - (iv) sampling and listing of in-process materials and drug products, yes or no? If no, document.
    - (v) time limitations on production, yes or no? If no, document.
    - (vi) control of microbiological contamination, yes or no? If no, document.
    - (vii) reprocessing, batching, yes or no? If no, document.
- (4) Packaging and Labeling Control:
- (a) Written procedures describing the receiving, identifying, storing, handling, sampling, testing, and approving or rejecting labels, yes or no? If no, document.
  - (b) Labeling and issuance: procedures written describing in detail the control procedure for the issuance of labeling, yes or no? If no document.

- (c) Packaging and labeling operations: written procedures to assure that correct labels, labeling and packaging are used for drug products, yes or no? If no, document.
- (5) Laboratory Controls:
- (a) Written procedures for sampling and testing plans, yes or no? If no, document.
  - (b) Procedures include:
    - (i) appropriate determination for conformance to final specifications for identity and strength of each active ingredient, yes or no? If no, document.
    - (ii) appropriate testing, as necessary, of each batch of drug product for microorganisms, yes or no? If no, document.
  - (c) Stability testing: a written testing program designed to assess the stability characteristics of drug products, yes or no? If no, document.
- (6) Reports and Records: Complaint files maintained which include written procedures for handling written and oral complaints regarding a drug product, yes or no? If no, document.
9. Warehouse (Sections 54.1-3435.4 and 54.1-3435.5 and Board Regulation 18 VAC 110-20-630):
- a. Permits/Licenses (Section 54.1-3430, Code of Virginia)
    - (1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the waiting or office area, yes or no? If no, document.
    - (2) Current (Sections 54.1-3430 and 54.1-3423): All permits and certificates current, yes or no? If no, document.
  - b. Restricted Access for Schedule II through V drugs (Board of Pharmacy Regulation 18 VAC 110-20-640)
    - (1) Access restricted in which Schedule II through V drugs are stored to a limited number of designated and necessary persons, yes or no? If no, document.
    - (2) Reasonable measures taken to prevent from pilfering drugs from the restricted areas, yes or no? If no, document.
  - c. Security System (Board of Pharmacy Regulations 18 VAC 110-20-640):
    - (1) A sound, microwave, or photoelectric device for detecting a breaking installed in each dispensing and drug storage area, yes or no? If no, document.
    - (2) Device maintained in operating order, yes or no? If no, document.
    - (3) Device protects the immediate storage and dispensing area, yes or no? If no,

document.

(4) Device has an auxiliary source of power, yes or no? If no, document.

10. Medical Equipment Suppliers (Section 54.1-3435.2 and 54.1-3435.3 and Board Regulation 18 VAC 110-20-630):

a. Permits/Licenses (Section 54.1-3430, Code of Virginia)

(1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the waiting or office area, yes or no? If no, document.

(2) Current (Sections 54.1-3430 and 54.1-3423): All permits and certificates current, yes or no? If no, document.

b. Physical Standard:

(1) Facility maintained in a clean and orderly manner, yes or no? If no, document.

(2) Storage area provides adequate lighting, ventilation, and temperature, yes or no? If no, document.

c. Security:

(1) Facility secured to prevent unauthorized entry, yes or no? If no, document.

(2) Access to prescription drugs limited to authorized personnel, yes or no? If no, document.

11. Practitioners Licensed to Sell Controlled Substances: [Board of Pharmacy Regulations 18 VAC 110-30-10]:

a. Permits/Licenses (Section 54.1-3430, Code of Virginia)

(1) Displayed (Section 54.1-3430): Each permit, license, and certificate must be posted for public view in a common area. A common area would be the waiting or office area, yes or no? If no, document.

(2) Current (Sections 54.1-3430 and 54.1-3423): All permits and certificates current, yes or no? If no, document.

b. Physical Standards for Controlled Substances Selling and Storage Area (Board of Pharmacy Regulation 18 VAC 110-30-90):

(1) Controlled Substances Selling and Storage Area [Board of Pharmacy Regulation 18 VAC 110-30-90.1]: Is the area designated as the controlled substances selling and storage area at least 60 square feet, yes or no? If no, document.

(2) Controlled Substances Maintained Separately [Board of Pharmacy Regulations 18 VAC 110-30-90.3]: Controlled substances for sale maintained separately from other controlled substances maintained for other purposes, yes or no? If no, document.

- (3) Counter Space: Board of Pharmacy Regulation 18 VAC 110-30-90.2]: Counter work space located in storage area, yes or no? If no, document. If the work counter space in the area is unclean and not orderly, the inspector will describe the conditions in the inspection report and will take photographs to substantiate the exact nature of the unsanitary conditions
  - (4) Sink: [Board of Pharmacy Regulation 18 VAC 110-30-90.2]: Is there a sink with hot and cold running water within the immediate selling and storage area, yes or no? If no, document.
  - (5) Lighting and Ventilation: [Board of Pharmacy Regulation 18 VAC 110-30-90.6]: Entire area well lighted and ventilated; proper storage temperature maintained to meet specifications for controlled substances, yes or no? If no, document.
- c. Access to Selling Area (Board of Pharmacy Regulation 18 VAC 110-30-100): Is access to stock rooms, rest rooms, and other areas other than an office for the license through the selling and storage area, yes or no? If no, document.
- d. Minimum Equipment (Board of Pharmacy Regulation 18 VAC 110-30-110):
- (1) Current copy of the U.S.P. Dispensing Information, yes or no? If no, document.
  - (2) Refrigerator with monitoring thermometer, in selling area, if any controlled substances require refrigeration, yes or no? If no, document.
  - (3) Current copy of the Drug Control Act and Board Regulations, yes or no? If no, document.
  - (4) Current copy of the Virginia Voluntary Formulary , yes or no? If no, document.
  - (5) Laminar Flow hood, if sterile product(s) are to be prepared, yes or no? If no, document.
  - (6) Prescription balance and weights, if engaged in extemporaneous compounding, yes or no? If no, document.
- d. Safeguard Against Diversion of Controlled Substances (Board of Pharmacy Regulations 18 VAC 110-30-120):
- (1) A sound, microwave, or photoelectric device for detecting a breaking installed in the controlled substances selling and storage area, yes or no? If no, document.
  - (2) Device maintained in operating order, yes or no? If no, document.
  - (3) Device fully protect the immediate controlled substance selling and storage area and capable of detecting breaking in the area when an area is closed, yes or no? If no, document.
  - (4) Alarm system has an auxiliary source of power, yes or no? If no, document.

(5) Alarm system activated and operated separately from any other alarm system in the area of business in which the controlled substance selling and storage area located, yes or no? If no, document.

(6) Alarm system controlled only by the license, yes or no? If no, document.

e. Selling Area Enclosures (Board of Pharmacy Regulation 18 VAC 110-20-130):

(1) Enclosures constructed in such a manner that it protects the controlled substance stock from unauthorized entry whether or not a licensee is on duty, yes or no? If no, document.

(2) Enclosure of sufficient height to prevent anyone from reaching over to gain access to the controlled substances, yes or no? If no, document.

(3) Entrance to enclosed area have a door which extends from the floor and which is at least as high as the adjacent counter or adjoining portions, yes or no? If no, document.

(4) Doors to area have adequate locking devices, yes or no? If no, document.

(5) Only licensee in possession of the alarm access code and any keys to the locking device on the door to such enclosure, yes or no? If no, document.

(6) If there is an emergency key and alarm access code to the enclosure, is it maintained in a sealed envelope, signed by a licensee, and placed in a safe or other secured place, yes or no? If no, document.

C. Reinspections: The inspector will inspect the deficiencies previously determined.

The inspector will state the deficiencies noted on the previous inspection and the current state of each corresponding item.

The inspector will also inspect the areas outlined in §VI-A. If the inspector observes an additional item in the inspection, the report shall be noted.

## VII. CONDUCT OF INSPECTORS DURING INSPECTION

Conduct of inspectors shall be as follows:

A. Proper introduction, using the Department's business card, if requested Department's identification badge.

B. Be polite and courteous.

C. Do not become argumentative over any issue.

D. Only inspect for the items listed on the inspection report form.

E. Be prepared to leave a copy of the regulations and law. Only direct the licensee to the regulation or law, if known. Contact the Board office if there are questions.

F. Do not answer questions relating to interpretations of laws, regulations, or policy issues. Direct all such questions to the Board administrator.

G. Do not suggest any actions, course of behavior, etc., as to how one will comply with the law or



regulation.

VIII. FREQUENCY OF INSPECTIONS

- A. Routine Inspections: A routine inspection of each licensed establishment, with the exception of medical equipment supplier will be conducted at least once every two years. This would create a two-year inspection rotation of all establishments, with the exception of medical equipment supplier.

Medical equipment suppliers will be inspected at least once every three years. This would create a three year rotation for medical equipment suppliers.

- B. New Facility Inspections: New establishment inspections will be conducted within five days of the specific date requested by the applicant, provided the application is received 60 days prior to the proposed opening date. After the initial inspection, new establishments will again be inspected within 12 months.
- C. Reinspection: Reinspections will be conducted at the request of the Board on those establishments receiving a letter from the Board as a result of deficiencies noted during the inspection.

For establishments with deficiencies corrected and no new violation, the establishment will be scheduled for a biennial inspection.

For establishments with deficiencies not corrected or a new violation(s) noted, a report will be provided to the Board for appropriate action.

IX. SELECTION OF FACILITIES FOR INSPECTION

- A. Routine Inspections: As stated in Section VIII, each establishment will be inspected at least once every two or three years.

Establishments inspected during an even month of a year will be reinspected during an odd month of the following scheduled inspection.

A list of establishments to be inspected in even and odd months will be provided to Inspectors by the Division’s supervisor. Enforcement Division may request an as part of an investigation.

- B. New Inspections and Reinspections: New inspections and reinspections will be conducted a request of the Board. The selection will be determined by the requested inspection date.

X. INSPECTION COSTS

A breakdown of the average time to conduct an inspection, average cost of an inspection, and annual cost of inspections is as follows.

- A. Average Time to Conduct Inspection

<u>Establishment</u>	<u>Shortest On-Site Time</u>	<u>Longest On-Site Time</u>	<u>Average On-Site Time</u>	<u>Average Travel</u>	<u>Total Average Time</u>
<u>Retail Pharmacy</u>					
New	1.0 hr	2.0 hrs	1.5 hrs	1 hr	2.5 hrs

Routine	1.5 hrs	2.5 hrs	2.0 hrs	1 hr	3.0 hrs
Reinspection	1.0 hr	3.0 hrs	2.0 hrs	1 hr	3.0 hrs

Hospital Pharmacy

New	1.5 hrs	2.5 hrs	2.0 hrs	1 hr	3.0 hr
Routine	2.5 hrs	4.5 hrs	3.5 hrs	1 hr	4.5 hrs
Reinspection	2.0 hrs	4.0 hrs	3.0 hrs	1 hr	4.0 hr

Physicians Licensed to Dispense Drugs

New	.5 hr	1.5 hrs	1.0 hr	1 hr	1.75 hrs
Routine	1.0 hr	2.0 hrs	1.5 hrs	1 hr	2.0 hrs
Reinspection	.75 hr	2.0 hrs	1.5 hrs	1 hr	2.5 hrs

Humane Societies

New	.5 hr	1.0 hr	.75 hr	1 hr	1.75 hrs
Routine	.75 hr	1.25 hrs	1.0 hr	1 hr	2.0 hrs
Reinspection	.75 hr	1.25 hrs	1.0 hr	1 hr	2.0 hrs

Wholesaler Distributor

New	1.0 hr	2.0 hr	1.5 hrs	1 hr	2.5 hrs
Routine	1.5 hrs	2.5 hrs	2.0 hrs	1 hr	3.0 hrs
Reinspection	1.5 hrs	2.0 hr	1.5 hrs	1 hr	2.5 hrs

Manufacturer

New	1.0 hr	2.0 hrs	1.5 hrs	1 hr	2.5 hrs
Routine	1.5 hrs	2.5 hrs	2.0 hrs	1 hr	3.0 hrs
Reinspection	1.5 hrs	2.0 hrs	1.5 hrs	1 hr	2.5 hrs

B. Average Cost to Conduct an Inspection

<u>Type of Establishment</u>	<u>Average* Hourly Rate</u>	<u>Average Hours to Conduct Inspection</u>	<u>Average Cost Per Inspection</u>
<u>Retail Pharmacy</u>			
New	\$67.58/hr	2.5 hrs	\$168.95
Routine	\$67.58/hr	3.0 hrs	\$202.74
Reinspection	\$67.58/hr	3.0 hrs	\$202.74
<u>Hospital Pharmacy</u>			
New	\$67.58/hr	3.0 hrs	\$202.74
Routine	\$67.58/hr	4.5 hrs	\$304.11
Reinspection	\$67.58/hr	4.0 hrs	\$270.32

Physicians Licensed to Dispense Drugs

New	\$43.79	2.0 hr	\$87.58
Routine	\$43.79	2.5 hrs	\$109.47
Reinspection	\$43.79	2.5 hrs	\$109.47

Humane Societies

New	\$43.79	1.75 hrs	\$76.63
Routine	\$43.79	2.0 hrs	\$87.58
Reinspection	\$43.79	2.0 hrs	\$87.58

Wholesale Distributors

New	\$43.79	2.5 hrs	\$109.47
Routine	\$43.79	3.0 hrs	\$131.37
Reinspection	\$43.79	2.5 hrs	\$109.47

Manufacturers

New	\$67.58/hr	2.5 hrs	\$168.95
Routine	\$67.58/hr	3.0 hrs	\$202.74
Reinspection	\$67.58/hr		\$168.95

Medical Equipment Supplier

New	\$43.79		\$76.63
Routine	\$43.79		\$87.58
Reinspection	\$43.79		\$87.58

Warehouseurs

New	\$43.79		\$109.47
Routine	\$43.79		\$131.37
Reinspection	\$43.79		\$109.47

\*The hourly rate is based on the operational cost of the Inspection Division. The rate will vary each month based on the Divisions' expenditures. The rate of \$67.58 for Pharmacy Inspectors and \$43.79 for Investigator B's is an average of July, August, and September 1993. The cost to the Board is determined by the Board's use of the Division.

C. Annual Cost of Inspections

<u>Type of Establishments</u>	<u>Total No. of Inspections</u>	<u>Total Hours to Inspect</u>	<u>Hourly Rate</u>	<u>Total Cost</u>
<u>Retail Pharmacy</u>				
New	50	125.0	\$67.58	\$8,447.50
Routine	480	1,440.0	\$67.58	97,315.20
Reinspection	<u>20</u>	<u>60.0</u>	<u>\$67.58</u>	<u>4,054.80</u>
Sub Total	550		\$67.58	\$109,817.50

Hospital Pharmacy

New	1	3.0	\$67.58	\$202.74
Routine	40	112.5	\$67.58	7,602.75
Reinspection	<u>1</u>	<u>4.0</u>	<u>\$67.58</u>	<u>270.32</u>
Sub Total	42	119.5	\$67.58	\$8,075.81

Physician Licensed to  
Dispense Drugs

New	10	2.0	\$43.79	\$875.8
Routine	25	62.5	\$43.79	2,736.87
Reinspection	<u>2</u>	<u>87.5</u>	<u>\$43.79</u>	<u>218.95</u>
Sub Total	37	87.5	\$43.79	\$2,517.92

Humane Societies

New	2	3.5	\$43.79	\$153.26
Routine	25	50.0	\$43.79	2,189.5
Reinspection	<u>2</u>	<u>4.0</u>	<u>\$43.79</u>	<u>218.95</u>
Sub Total	29	57.5	\$43.79	\$2,517.92

Wholesale Distributors

New	2	5.0	\$43.79	\$168.95
Routine	30	90.0	\$43.79	3,8582.06
Reinspection	<u>1</u>	<u>2.5</u>	<u>\$43.79</u>	<u>168.95</u>
Sub Total	33	97.5	\$43.79	\$4,189.92

Manufacturers

New	1	2.5	\$67.58	\$168.95
Routine	19	57.0	67.58	3,852.06
Reinspection		<u>2.5</u>	<u>67.58</u>	<u>168.95</u>
Sub Total	20	62.0	\$67.58	\$4,189.92

Medical Equipment  
Suppliers

New	5	8.75	\$43.79	\$383.16
Routine	34	68	\$43.79	2,977.72
Reinspection	<u>1</u>	<u>2.0</u>	<u>\$43.79</u>	<u>87.58</u>
Sub Total	40	78.75	\$43.79	\$3,448.46

Warehouser

New	1	2.5	\$43.79	\$109.47
Routine	4	10.0	\$43.79	437.90
Reinspection	<u>1</u>	<u>2.5</u>	<u>\$43.79</u>	<u>109.47</u>
Sub Total	6	15.0	\$43.79	\$646.84
Total	767	2124.75		\$136,807.59

XI. INSPECTION REPORT FORM

- A. All routine, new, and reinspections will be conducted on the Board of Pharmacy Inspection Report Form, and any addendum will be attached to the inspection report.
- B. Upon completion of the inspection, the inspector will:
  - 1. leave the inspection report with the pharmacist or other employee in charge of the establishment;
  - 2. leave a compliance notice with the pharmacist , if applicable;
  - 3. respond to questions relating to the facts reflected in the inspection report;
  - 4. obtain signature of a pharmacist or other person employed by the establishment on the inspection form; and
  - 5. submit the white or original sheet of the inspection report form, and any addendum, to the Inspection Division; leave the yellow copy with the permit holder, and retain the pink copy.
  - 6. mail new facility reports to the office of the Inspection Division before 5 p.m. the day of the inspection
- C. The Inspections Division shall deliver the new facility inspection report to the Board office the same day it is received.
- D. The Inspection Division will forward the inspection report form to the Board within two days of its receipt.
- E. The Inspection Division will maintain a separate file on each establishment inspection.

XII. EVALUATION OF INSPECTION PLAN

- A. Number of deficiencies cited per inspection. A comparison of this data will be made with the previous year's data. A 50-percent decrease in cited deficiencies would indicate the inspection program was gaining voluntary compliance with the laws and regulations.\*
- B. Total number of deficiencies cited for all inspections. A comparison of this data will be made with the previous year's data. A 50-percent decrease in cited deficiencies would indicate the inspection program was gaining voluntary compliance with the laws and regulations.\*
- C. Number of hearing conducted, compliance letters sent to licensees, and reinspections resulting from inspections. A comparison of this data will be made with the previous year's data. A 30-percent decrease in hearings conducted would indicate a decrease in the seriousness of cited

deficiencies; a 20-percent decrease in compliance letters and reinspections would indicate a decrease in seriousness and number of deficiencies.\*

### XIII. SUMMARY REPORT

Provide quarterly summary reports to the Board that would contain the following:

A. Break-down of Types and Number of Inspections Conducted

1. New
2. Routine
3. Re-inspection
4. Total of all inspections

B. Board Actions

1. Informal conference
2. Compliance letters

C. Number of Cases Initiated by Inspections

D. Number of Deficiencies Cited by Inspections

\*Alternatively, a decrease could indicate inspectors are not as vigorous or aggressive in conducting inspections. All the data in A, B, & C needs to be reviewed in combination.

**Revised 7/1/99**