

VIRGINIA BOARD OF PHARMACY

Information for Applicants for Pharmacist Licensure

1. Licensure by Examination:

Application

The application form is available on the Board of Pharmacy website at www.dhp.virginia.gov/pharmacy, it must be completely executed, and must be sent with the fee as designated on the form to the address on the form. Incomplete applications will be promptly returned.

Practical Experience Requirements

An applicant shall accumulate a minimum of 1,500 hours of practical experience to include no less than 300 hours in the area of compounding and dispensing, except that students having graduated from an approved school of pharmacy prior to January 1, 2003 shall have gained at least 1,000 hours of practical experience. Credit will not be given for more than 50 hours in any one week. The 1,500 hours may include hours gained within an approved school clerkship program, however, at least 300 hours of the 1500 hour requirement shall be gained outside of a school of pharmacy practical experience program. All practical experience hours used in meeting this requirement must be gained after the first professional year of pharmacy school and within the United States.

Certificates of Practical Experience

- For practical experience gained within the college experiential program, documentation should be recorded and certified under the "College Affidavit" section of the application. No further affidavits are needed for this experience.
- Affidavits of experience gained in Virginia, outside the college experiential program, must be signed by the supervising pharmacists, and attached to the application (if not previously submitted to the Board). Currently for experience gained outside the school curriculum, no pharmacist may supervise more than one intern during a given time period for the experience.
- Certificates or documentation of practical experience gained in another state must be certified by the board of pharmacy in that state and must be received by this Board directly from that state. This documentation must show actual dates of employment, total hours worked, place of employment and name of supervising pharmacists, and the certifying Board shall verify current, unrestricted licensure status of the supervising pharmacists.

Taking the NAPLEX

Applicants must directly register with and pay the required fee to the National Association of Boards of Pharmacy (NABP) in order to take the NAPLEX examination at www.nabp.net. NAPLEX is the competency assessment examination for initial pharmacist licensure that is accepted by all 50 states, the District of Columbia, and Puerto Rico. An applicant may either take NAPLEX in Virginia, or register with NABP to score transfer to Virginia. However, you will not be allowed to schedule taking NAPLEX until you have been approved by the Board.

The Board notifies NABP once a week of any applicants that have registered with NABP and have been approved by the Board. Unless there are problems with an application, the application is usually approved within a day or two of receipt by the Board, a letter of approval is sent to the applicant, and the approval forwarded to NABP during the weekly submission following the approval. Additional details about NAPLEX are also available on the NABP website.

Taking the Virginia pharmacy law examination

Virginia does not use the MPJE. Once an application has been approved, the Board will notify the applicant by letter of the approval, and also notify the contractor for the law examination of such approval. The applicant must make arrangements directly with that testing contractor to pay the fee and schedule the examination. Instructions for doing this are sent in the approval letter and are also in the study guide. The law exam may be taken either before or after the NAPLEX. The examination is a computerized examination that the applicant may schedule at any time that the requested testing center is open and has availability. There are testing centers in various parts of Virginia and throughout the United States. **An electronic version of the study guide, that identifies applicable sections of law and regulation, is attached to this guidance document. Applicable state laws and regulations are on the Board's website, and applicable sections of federal law may also be found on the internet by searching for the Code of Federal Regulations or U.S. Code or U.S. Public Law.**

Grounds to deny a license

If the Board determines that grounds may exist to deny an application for licensure as a pharmacist, the application will not be approved by board staff, and the applicant so notified and offered an opportunity to meet with an informal conference committee of the Board to determine if the license should be denied, issued, or issued conditionally. Grounds to deny a license may be found in §54.1-3316 of the Code of Virginia on the Board's website.

2. Reciprocity or Licensure by Endorsement:

Virginia does allow licensure by a process called endorsement in which an applicant may transfer a pharmacist license from another state, provided the applicant's credentials for licensure in the other state meet Virginia's credentialing requirements with respect to education, practical experience, and required examinations, and provided grounds do not exist to deny an application such as disciplinary action by another state or criminal convictions. Applicants will need to go through the NABP license transfer process in order to do this. Instructions and forms for this may be found at www.nabp.net. Once the preliminary application and fee is submitted to NABP, NABP will partially complete the official application for Virginia, and send it back to the applicant. Then the applicant finishes completing the form and submits it to the Virginia Board of Pharmacy. Once the application has been received by this Board and approved, the applicant will then be approved to take the Virginia law exam and notified by letter of such approval with instructions as to how to pay for and schedule the exam. Virginia does not use the MPJE.

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Virginia Board of Pharmacy

**FEDERAL AND
STATE DRUG LAW
EXAMINATION
HANDBOOK**



June 2009

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Contacts

All questions about the FSDLE written examinations should be directed to:

Comira
1801 Murchison Drive, Suite 288
Burlingame, CA 94010
Phone: 800-947-4228
Fax: 650-692-9537

Questions about licensing should be directed to:

Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
Phone: 804-367-4456
Fax: 804-527-4472

FSDLE GUIDE AND INFORMATION

This Handbook will provide you with the necessary information regarding scheduling your Virginia Federal and State Drug Law Examination (FSDLE).

Purpose of Examination

Pharmacists, among all the health professionals, are entrusted with the most important drug control responsibilities. To ensure entry-level competence, the Virginia Board of Pharmacy administers a combined federal and state drug law examination. A single examination tests candidates' knowledge of Federal Drug Law and Virginia Pharmacy Law and Regulations.

Scheduling your FSDLE Exam through Comira

The state of Virginia has contracted with Comira to conduct its examination program. You may be able to register for your FSDLE Exam at any of Comira's testing locations. Locations can be found by visiting their website at www.comiratesting.com or by calling their toll free registration number at: 800-947-4228 between 9 a.m. and 8 p.m. (Eastern Time) Monday through Friday and between 11 a.m. and 3 p.m. on Saturday.

Appointments are available Monday through Friday at most testing centers with some weekend availabilities. Comira recommends scheduling your exam at least 3 days prior to your exam date.

Same-day walk-in registration: If an appointment time is available, you can register at the site and take your test immediately.

Canceling or rescheduling your exam. Comira requires a 24-hour cancellation or rescheduling policy. In the event of an

emergency on the day of the exam please contact both the Testing Location and Comira. Failure to notify Comira in a timely manner may result in forfeiting your exam fee.

At the time of registration you will be asked a series of questions:

- When – The day and time you wish to take your exam.
- Where – The location of the Testing Center.
- Payment – You may be able to pay the \$100 Testing Fee with a personal credit card over the phone. For other means of payment contact the Comira's Registration Department.
- Full Legal Name – Your official name on record given to the Virginia Board of Pharmacy.
- Social Security number or Virginia DMV control number – This is your personal identification number that will be used by both the Virginia Board of Pharmacy and Comira.

Comira's testing computers are secured and protected as U.S. Government *For Official Use Only* information. All FSDLE data is the property of the Virginia Board of Pharmacy and may not be used for any other purpose than authorized by this order.

Format of the FSDLE and Fees

The exam consists of 100, multiple-choice questions. It includes several simulations of prescriptions, labels, and refill records. Only one correct response exists for each question. Candidates are given two hours for its completion. A passing score of 75 is

required. The fee for this exam is \$100 and payable to Comira at the time of registration.

Taking the Examination

Your examination will be administered via computer at a Comira Testing Center. You should arrive 15 minutes prior to your schedule appointment to allow you to sign in, verify your Identification, and allow you to familiarize yourself with the software. You do not need any computer experience or typing skills to take the exam. You will have available to you a demo test that will familiarize you with the testing software and its features. This demo test does not count toward the time allowed to take your FSDLE exam.

Identification

Prior to test administration you must provide the testing center positive identification. The identification presented must include a current photograph, full legal name as submitted during registration, signature, and social security number or Virginia DMV control number. This information may be presented in more than one form of identification.

Acceptable forms of Identification include driver's licenses, government identification cards, passports, alien residency cards, and military identification.

Failure to provide appropriate identification at the time of examination will be considered a missed appointment.

For additional information on identification and authorization please contact Comira before scheduling your exam.

Special Accommodations

Should you require special accommodations please contact the Virginia Board of Pharmacy prior to scheduling your exam.

Survey

At the end of your exam you will be asked a series of questions regarding your overall testing experience. All completed surveys are forwarded to the Virginia Board of Pharmacy and Comira for further evaluation.

Exam Results

At the end of your exam you will be issued a pass/fail letter. You will then sign out on the daily sign in/out log. If successful in passing, you will receive your license to practice from the Virginia Board of Pharmacy within one week. The pass letter is not considered authorization to begin practicing.

Retesting

If you fail the exam you may retake it after a 5-day waiting period. Please contact Comira to schedule your retake. You will be required to pay the examination fee of \$100 each time the test is administered.

How to Use This Study Guide

Be sure to obtain all references listed for the examination. The supplemental references listed herein are highly recommended. You should become thoroughly familiar with the study guide. To prepare for the examination the candidate is referred to the behavioral objectives for a description of the exam's content.

You should recognize that the list of competencies or behavioral objectives in this guide specifies the title, chapter, and section number of the law and regulations for which test questions exist. Only specified sections within each chapter of the law are tested. While emphasis should be placed on the sections specifically indicated, it is recommended that you master all the relevant law and regulations for full comprehension.

The examination covers all state and federal law and regulations required for competent entry-level practice. Since much of state drug law duplicates federal law, emphasis is placed on state law, and where possible, information is referenced to state law rather than to federal law. Specific mention of titles, chapters, and sections of federal drug law is limited to those areas of federal law not already covered within the body of state specific law.

It is recommended that you supplement your study of pharmacy law by reading additional text books, journals, and related academic course materials.

Recognize that laws, rules, and standards are modified from time to time, and it is your responsibility to keep your knowledge current during the course of your future professional practice.

Candidate Study Guide

Federal and State Drug Law Exam (FSDLE)

List of References

1. *Code of Virginia*
Pharmacy, General Provisions
(54.1-3300 through 54.1-3319)
2. Board of Pharmacy Regulations
(18 VAC 110-20-10 through
18VAC 110-20-680)
3. *Code of Virginia*
Drug Control Act
(54.1-3400 through 54.1-3472)
4. *Code of Virginia*
Crimes Involving Health & Safety
(18.2-247 through 18.2-265)
(18.2-8 through 18.2-16)
5. *Code of Virginia*
Department of Health Professions
General Provisions
(54.1-2400 through 54.1-2409)
6. *Code of Virginia*
Department of Health Professions
(54.1-2500 through 54.1-2510)
7. *Federal Controlled Substance Act*
(21 USC 801 et seq)
(21 CFR 1301 et seq)
8. *Federal Food, Drug, and Cosmetic Act*
(FDCA)
(21 USC 301 et seq)
9. *Prescription Drug Marketing Act of 1987*
(21 USC 353)

Suggested Supplemental References

1. *Pharmacy Law Digest*
Facts and Comparisons, Inc.
111 West Port Plaza, Suite 400
St. Louis, MO 63146-3098
800.223.0554

Website Links

VIRGINIA BOARD OF PHARMACY: www.dhp.virginia.gov/pharmacy
Click on Laws and Regulations

UNITED STATES CODE: <http://www.gpoaccess.gov/uscode/index.html>

CODE OF FEDERAL REGULATIONS: <http://www.gpoaccess.gov/cfr/index.html>

Federal And State Drug Law Exam (FSDLE) Content Outline

I. LICENSING, REGISTRATION, AND INSPECTION (24%)

- A . Obtain, renew, and maintain pharmacist license
 - 1. Describe the requirements and procedures involved in obtaining and renewing a pharmacist license (54.1-3310, 54.1-3311, 54.1-3312, 54.1-3313, 54.1-3314, 18 VAC 110-20-20, 18 VAC 110-20-30, 18 VAC 110-20-40, 18 VAC 110-20-50, 18 VAC 110-20-60, 18 VAC 110-20-70, 18 VAC 110-20-80)
 - 2. Explain the requirements for completing continuing education and maintaining documentation (54.1-3314.1, 18 VAC 110-20-80, 18 VAC 110-20-90, 18 VAC 110-20-100)
 - 3. Explain dispensing activities which are restricted to pharmacists (54.1-3320, 18 VAC 110-20-270)
 - (a) Describe registration procedures for obtaining and renewing registration for pharmacy technicians (54.1-3321, 18 VAC 110-20-101, 18 VAC 110-20-105, 18 VAC 110-20-106)
 - (b) Explain authorized duties of registered pharmacy technicians (54.1-3321, 18 VAC 110-20-111, 18 VAC 110-20-270)
 - (c) Explain requirements and responsibilities for supervising intern practical experience (54.1-3320 (B), 54.1-3321(C), 18 VAC 110-20-40(B))
 - (d) Explain scope of practice
 - (i) Practice of pharmacy (54.1-3300, 54.1-3408 (I))
 - (ii) Pharmacy intern (54.1-3300)
 - (iii) Pharmacy technician (54.1-3300)
 - (iv) Supervision, personal supervision (54.1-3300, 18 VAC 110-20-10)
- B . Maintain standards of legal and professional conduct
 - 1. Explain grounds for disciplinary action
 - (a) List the grounds for revocation or suspension of a pharmacist's license or of a pharmacy permit (54.1-3315, 54.1-3316, 54.1-2408.1, 54.1-2409)
 - (b) Recognize requirement to maintain patient confidentiality (32.1-127.1:03)
 - (c) Describe prohibitions regarding patient's right to choose and disclosure of kickbacks, fee-splitting (18 VAC 110-20-390)
- C . Obtain, renew, and maintain pharmacy permits
 - 1. Explain the requirements and procedures involved in obtaining and renewing a pharmacy permit (54.1-3434, 18 VAC 110-20-20, 18 VAC 110-20-110, 18 VAC 110-20-120)
 - (a) File application to open a new pharmacy, change location of an existing pharmacy, or make structural changes to a prescription department (54.1-3434, 18 VAC-110-20-140)

- (b) Describe the requirements for display of pharmacy permit (54.1-3430)
- (c) Describe the responsibilities for the pharmacist in charge (54.1-3432, 54.1-3434, 18 VAC 110-20-110, 18 VAC 110-20-440)
- 2. Meet physical requirements, restrict access and maintain proper storage and security of all Schedule II-VI controlled substances and devices
 - (a) Explain the requirements for physical standards and minimum required equipment for pharmacies (18 VAC-110-20-150, 18 VAC 110-20-160, 18 VAC-110-20-170)
 - (b) Explain the requirements for enclosures to the prescription department (as defined in regulation) and access to the prescription department both in the presence or absence of a pharmacist (18 VAC 110-20-10, 18 VAC 110-20-190)
 - (c) Explain the requirements for an alarm system and when it should be activated (18 VAC 110-20-180)
 - (d) Explain the requirements for appropriate storage for drugs, devices, controlled substances, and expired drugs (18-VAC 110-20-200)
 - (e) Explain the requirements for drug storage and security, outside the pharmacy, throughout hospitals and long term care facilities (18 VAC 110-20-420(A)(1), 18 VAC 110-20-440, 18 VAC 110-20-530 (3-6), 18 VAC 110-20-470(1))
 - (f) Explain requirements and documentation for managing after-hours access to the pharmacy in a hospital (18 VAC 110-20-450)
- 3. Explain the procedures for closing a pharmacy, changing hours of operation, and appropriate disposition of drugs and records (54.1-3434, 54.1-3434.01, 18 VAC 110-20-130, 18 VAC 110-20-135)
- D . Comply with inspection authority of the Board of Pharmacy and the State Police
 - 1. Describe powers of inspection and inspection procedures and access to records by board agents and state police (54.1-3307, 54.1-3308, 54.1-3405)
 - 2. Describe access to prescription records during inspections (54.1-3405)
- E . Comply with DEA and FDA requirements
 - 1. Determine the need for and describe the procedures involved in obtaining and renewing DEA registration (21 CFR 1301)
 - 2. Explain the regulations governing discontinuance of practice (21 CFR 1301.52, 21 CFR 1307.21)
 - 3. Explain the requirements for registration modification and transfer (21 CFR 1301.51, 21 CFR 1301.52)
 - 4. Describe powers of inspection, inspection procedures, access to records by DEA and FDA agents, and rights of pharmacists (21 CFR 1316, 21 USC 360(h), 21 USC 374))

5. Understand the restrictions which are imposed on the hiring of persons having access to Schedule II-V controlled substances (21 CFR 1301.76)

II. ORDERING, RECEIVING, AND MANAGING DRUG INVENTORY (21%)

A . Ordering and receiving controlled substances

1. Determine the conditions for legally transferring Schedule II-VI controlled substances between registrants (54.1-3414, 54.1-3415, 54.1-3435.02)
2. Explain the use of official DEA order forms in ordering and transferring Schedule II controlled substances (21 CFR 1305)
3. Explain the conditions under which drugs may be ordered or purchased (18-VAC 110-20-395, 21 USC 353)
4. Explain requirements for maintaining records of receipt for Schedule II-V controlled substances (54.1-3404(C), 18 VAC 110-20-240(A), 21 CFR 1305.13)

B . Inventory

Perform inventory of Schedule II-V controlled substances and describe the inventory requirements for Schedule II-V controlled substances, in terms of dates, required records, format, count requirements, filing, and newly scheduled drugs (54.1-3404 (A and B), 54.1-3434, 18 VAC 110-20-110(C), 18 VAC 110-20-240(A))

C . Maintain drug integrity

1. Ensure and maintain integrity of drug product
 - (a) Evaluate drugs to determine whether they meet all legal requirements for selling, distributing, or dispensing and recognize the conditions under which drugs are adulterated or misbranded while being held for dispensing (54.1-3461, 54.1-3462)
 - (b) Understand the following terms necessary for proper drug storage
 - (i) Proprietary medicine (54.1-3401)
 - (ii) Light resistant container (18 VAC 110-20-10)
 - (iii) Storage temperature (18 VAC 110-20-10)
 - (iv) Tight container (18 VAC 110-20-10)
 - (v) Unit dose container (18 VAC 110-20-10)
 - (vi) Unit dose package (18 VAC 110-20-10)
 - (vii) Unit dose system (18 VAC 110-20-10)
 - (viii) Well-closed container (18 VAC 110-20-10)
 - (ix) Compliance packaging (18 VAC 110-20-10)
 - (x) Prescription drug (21 USC 353(b))
 - (xi) US Pharmacopeia drugs (21 USC 321)
 - (xii) Veterinary pharmaceuticals (21 USC 353(f))
 - (xiii) New drug (21 USC 321(p))
 - (xiv) Nonprescription drug (21 CFR 330)
 - (xv) Investigational new drug (21 CFR 312.3(b))

- (c) Explain the conditions under which drugs and devices previously dispensed may be accepted for return to stock for resale (54.1-3411.1, 18 VAC 110-20-400)
 - (d) Repackage and label prescription drugs
 - (i) Explain packaging and labeling requirements to include determination of appropriate expiration date for repackaged drugs (18 VAC 110-20-355(B))
 - (ii) Explain records required for reconstitution, bulk compounding, and repackaged drugs (18 VAC 110-20-355(A))
 - (iii) Explain requirements for use of automated counting or dispensing devices (18 VAC 110-20-355(C))
- D . Provide for proper disposal of drugs
1. Properly dispose of Schedule II through V controlled substances (54.1-3417, 18 VAC 110-20-210)
 - (a) Identify the procedure for the destruction or disposition of unwanted Schedule II-VI controlled substances (54.1-3417, 18 VAC 110-20-210)
 - (b) Explain record keeping requirements (54.1-3404(D), 18 VAC 110-20-210)
 2. Explain the requirements for disposition of discontinued drugs for long term care facilities, to include records (18 VAC 110-20-530(7)(A-D))
- E . Report stolen or lost drugs
1. Explain the reporting requirements for theft or loss of Schedule II-V controlled substances (54.1-3404(E), 21 CFR 1301.76)
 2. Explain the conditions under which an inventory needs to be taken following a drug loss (54.1-3404(E))
 3. Describe record keeping requirements for loss of drugs (54.1-3404(E-F))

III. REVIEW PRESCRIPTIONS (30%)

- A . Receive prescriptions and orders
1. Describe the general requirements for receipt and documentation of oral prescriptions (54.1-3320 (2), 54.1-3410(B), 54.1-3410(D), 54.1-3411, 18 VAC 110-20-290(C), 18 VAC 110-20-420(A)(2), 54.1-3408.01 (C))
 2. Describe conditions under which a prescription may be faxed or electronically transmitted (18 VAC 110-20-280, 18 VAC 110-20-285)
 3. Explain the requirements for transferring prescriptions between pharmacies (18 VAC 110-20-360)
 - (a) Explain the limitation for transferring a prescription for Schedule III-V controlled substances for refill purposes (21 CFR 1306.25)
 4. Explain the requirements for obtaining, recording, and maintaining patient information (54.1-3319(D))
- B . Review prescription orders
1. Review prescriptions for legality

- (a) Ensure that prescriptions are written in good faith within the context of a bona fide physician-patient relationship for a medicinal or therapeutic purpose (54.1-3303(A-B), 54.1-3408)
 - (b) Determine whether a prescription is written within a prescriber's authority and scope of practice (54.1-3303(A-E))
 - (c) List which health care practitioners have prescriptive authority in Virginia (54.1-3303(A, D, E, F), 54.1-3401, 54.1-3408))
 - (d) Describe the conditions under which an out-of-state prescription may be filled (54.1-3303(C))
 - (e) Discuss the limitations upon accepting prescriptions from medical interns or residents and the purpose of the suffix assigned to the intern or resident for prescribing Schedule II-V controlled substances (18 VAC 100-20-510)
 - (f) Describe the method for handling prescriptions that are declined for reasons other than nonavailability of the drug (18 VAC 110-20-270(D))
 - (g) Identify the schedules of commonly used drugs as listed in Appendix A
 - (h) Explain the criteria used for the general classification of Schedule I-V controlled substances (54.1-3443(A), 21 USC 811(c))
 - (i) Explain the restrictions on dispensing narcotics for the purpose of maintenance or detoxification (21 CFR 1306.07)
 - (j) Explain the conditions under which a pharmacist may engage in generic substitution (54.1-3408.03, 54.1-3401 (Definition of therapeutically equivalent drug products))
2. Review prescriptions for required elements
- (a) Describe the information that must appear on any prescription (54.1-3408.01, 54.1-3409, 54.1-3410)
 - (b) Identify any additional information required for a valid prescription for a Schedule II-V controlled substances (54.1-3408.01(A), 21 CFR 1306.05))
3. Conduct drug use reviews
- (a) Describe the requirements for conducting a prospective drug review prior to dispensing (54.1-3319(A))
 - (b) Describe the requirements for performing monthly reviews of drug therapy for patients in a hospital or long term care facility (18 VAC 110-20-440(B), 18 VAC 110-20-530(9))
- C . Explain requirements for central or remote processing of prescriptions (18 VAC 110-20-276, 18 VAC 110-20-515)

IV. DISPENSING AND DISTRIBUTION (25%)

A . Dispensing drugs pursuant to a prescription

- 1. Describe the appropriate terms necessary for lawful dispensing
 - (a) Repackaged drug (18 VAC 110-20-10)
 - (b) Safety closure container (18 VAC 110-20-10)
 - (c) Special packaging (18 VAC 110-20-10)

- (d) Terminally ill (18 VAC 110-20-10)
 - (e) Compounding (54.1-3401)
 - (f) Device (54.1-3401)
 - (g) Dispense (54.1-3401)
 - (h) Drug (54.1-3401)
 - (i) Administer (54.1-3401)
 - (j) Label (54.1-3401)
 - (k) Labeling (54.1-3401)
 - (l) Prescription (54.1-3401)
 - (m) Schedule VI device (54.1-3455)
 - (n) Schedule VI (54.1-3455)
 - (o) Controlled substance (54.1-3401)
 - (p) Controlled substance (21 USC 802(6), 21 CFR 290.1))
 - (q) Drug sample (21 USC 353, 21 CFR 203.3(aa))
2. Explain the conditions under which prescriptions for Schedule II controlled substances may be filled to include time limitations and conditions for partial filling (54.1-3410(A)(1-2), 54.1-3411(1), 18 VAC 110-20-290, 18 VAC 110-20-310))
 3. Explain the conditions under which prescriptions for Schedule III-V controlled substances may be filled or refilled to include time limitations, restrictions, and requirements for partial filling (54.1-3410(B), 54.1-3411(2), 18 VAC 110-20-320(A,D))
 4. Explain the conditions under which prescriptions for Schedule VI controlled substances may be filled or refilled to include time limitations (54.1-3410(B, C), 54.1-3411(2,3,4) 18 VAC 110-20-320(B,D))
 5. Describe the records required for dispensing Schedule II-VI controlled substances and methods of filing (54.1-3404 (D and F), 54.1-3410, 54.1-3411, 54.1-3412, 18 VAC 110-20-240, 18 VAC 110-20-250, 18 VAC 110-20-255, 18 VAC 110-20-320))
 6. Explain how to properly package prescriptions (54.1-3426, 54.1-3427, 18 VAC 110-20-340, 18 VAC 110-20-350)
 7. Explain how to properly label prescriptions (54.1-3410(A)(3), 54.1-3410 (B)(2), 54.1-3463(A), 18 VAC 110-20-330))
 - (a) Explain caution label requirement for Schedule II-V controlled substances (21 CFR 290.5)
 8. Explain requirements for making an offer to counsel and describe the components of counseling (54.1-3319(B-E))
 9. Explain requirements for compounding (54.1-3401, 54.1-3410.2)
- B . Dispensing or distributing drugs by other methods
1. Explain dispensing unit dose system (18 VAC 110-20-420)
 2. Explain procedures and required records for dispensing drugs for floor stock, licensed emergency medical services agencies, emergency drug kits, and stat drug boxes (18 VAC 110-20-460, 18 VAC 110-20-500, 18 VAC 110-20-540, 18 VAC 110-20-550, 18 VAC 110-20-560, 18 VAC 110-20-590(B))

3. Explain procedures and required records for dispensing drugs from automated dispensing devices (54.1-3434.02, 18 VAC 110-20-490, 18 VAC 110-10-555)
 4. Describe the requirements for delivery of dispensed prescriptions (54.1-3420.2, 18 VAC 110-20-275)
 5. Explain the conditions under which insulin can be dispensed (54.1-3419)
 6. Describe the conditions and documentation for sale of controlled paraphernalia (54.1-3467, 54.1-3468, 54.1-3469)
 7. Explain the conditions and documentation for dispensing Schedule V controlled substances without a prescription (54.1-3416)
- C . Prescription monitoring program
1. Describe requirements for reporting covered substances (54.1-2519, 54.1-2520, 54.1-2521, 54.1-2522, 18 VAC 76-20-30, 18 VAC 76-20-40)
 2. Describe confidentiality of data and disclosure of information (54.1-2523.1, 54.1-2525, 18 VAC 76-20-50, 18 VAC 76-20-60)

APPENDIX A

The sections of Virginia law listing drugs within the various schedules are confusing and typically include legal or chemical names. For this reason, Appendix A was developed to assist you in studying this portion of the law for the examination. Appendix A is a listing of drug schedules and some generic and brand names of commonly dispensed drugs in each schedule in addition to some common professional suffixes. Drug names or professional suffixes included in the examination, which require or test for this knowledge, will be taken from this list.

PROFESSIONAL SUFFIXES

MD- Doctor of Medicine
OD- Doctor of Optometry
DC- Doctor of Chiropractic
DDS- Doctor of Dental Surgery
PA- Physician Assistant
RN- Registered Nurse

DPM- Doctor of Podiatric Medicine
DO- Doctor of Osteopathic Medicine
DVM- Doctor of Veterinary Medicine
DMD- Doctor of Dental Medicine
NP or LNP- Nurse Practitioner
LPN- Licensed Practical Nurse

SCHEDULE I:

Schedule I drugs are drugs which have a high potential for abuse, but which have no accepted medical use in treatment in the United States or which lack accepted safety for use in treatment even under medical supervision.

SCHEDULE II:

GENERIC NAME	SOME BRAND NAMES
meperidine	Demerol
morphine sulfate	M.S. Contin, Roxanol
oxycodone	Percodan, Percocet, Tylox, OxyContin
hydromorphone	Dilaudid
methadone	Dolophine
codeine (as a single drug entity)	
fentanyl	Sublimaze
alfentanyl	Alfenta
sufentanil	Sufenta
opium	

cocaine	
methylphenidate	Ritalin
amphetamine	Biphedamine
dextroamphetamine	Dexedrine
phenmetrazine	
methamphetamine	Desoxyn
pentobarbital (suppositories are schedule III)	Nembutal
secobarbital (suppositories are schedule III)	Seconal
amobarbital (suppositories are schedule III)	Amytal

SCHEDULE III:

GENERIC NAME	SOME BRAND NAMES
codeine in combination with acetaminophen	Tylenol with codeine #2, #3, #4; Phenaphen with codeine #2, #3, #4
codeine in combination with aspirin	Empirin with codeine #2, #3, #4
hydrocodone	Tussionex, Vicodin, Lorcet Plus, Lortab, Hycodan, Zydone, Anexsia
butabarbital	Butisol
butalbital (unless in combination with acetaminophen, then schedule VI)	Fiorinal, Fiorinal with codeine
thiopental sodium	Pentothal
benzphetamine	Didrex
phendimetrazine	Bontril, Prelu-2
nandrolone	Anabolin, Androlone, Deca-Durabolin, Durabolin, Hybolin, Nandrobolic
stanozolol	Winstrol
oxandrolone	Anavar
Dronabinol	Marinol

SCHEDULE IV:

GENERIC NAME	SOME BRAND NAMES
diazepam	Valium
lorazepam	Ativan
alprazolam	Xanax
chlordiazepoxide	Librium
oxazepam	Serax
prazepam	Centrax
triazolam	Halcion
clonazepam	Klonopin
chlorazepate	Tranxene
flurazepam	Dalmane
zolpidem	Ambien
temazepam	Restoril
phenobarbital	
pentazocine	Talwin
propoxyphene	Darvon
phentermine	Fastin, Ionamin, Adipex-P
diethylpropion	Tepanil, Tenuate
fenfluramine	Pondimin
mazindol	Sanorex

SCHEDULE V:

GENERIC NAME	SOME BRAND NAMES
most cough syrups containing codeine	
diphenoxylate	Lomotil

SCHEDULE VI:

All prescription drugs and devices which have not been placed in another schedule are in Schedule VI. This includes any drug or device which is not in another schedule, but which is required by federal law to bear on its label one of the following legends:

1. "Rx only" or "Caution: Federal Law Prohibits Dispensing Without Prescription"
2. "Caution: Federal Law Restricts This Device To Sales By Or Use On The Order Of A Physician"
3. "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian"

Schedule VI also includes any drug not listed in Schedules I - V which because of toxicity, potential for harm, method of use, or collateral measures necessary to its use is not generally recognized among experts as being safe for use except by or under the supervision of a practitioner licensed to prescribe.

<i>GENERIC NAME</i>	<i>SOME BRAND NAMES</i>
digoxin	Lanoxin
penicillin v.	Penicillin VK
bupropion hydrochloride	Wellbutrin
amoxicillin	Amoxil
cephalexin	Keflex
tramadol hydrochloride	Ultram

APPENDIX B

I

U.S. CODE TITLE 21 FOOD AND DRUGS

UNITED STATES CODE:

<http://www.gpoaccess.gov/uscode/index.html>

(Use the Browse feature)

CHAPTER 9 – FEDERAL FOOD, DRUG AND COSMETIC ACT

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353a	Pharmacy compounding
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CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL

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CODE OF FEDERAL REGULATIONS (CFR)

TITLE 21 CFR FOOD AND DRUGS

<http://www.gpoaccess.gov/cfr/index.html>

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CHAPTER 1

Part 290	Controlled drugs
Part 310	New drugs
Part 330	Over-the-counter human drugs

CHAPTER 2

Part 1301	Registration of manufacturers, distributors and dispensers of controlled substances
Part 1302	Labeling and packaging for controlled substances
Part 1304	Records and reports of registrants
Part 1305	Order forms
Part 1306	Prescriptions

Part 1307
Part 1308
Part 1316

Miscellaneous
Schedules of controlled substances
Administrative functions, practices, and procedures

THE PHARMACIST'S MANUAL
(from the United States Drug Enforcement Agency Diversion Control Program)
<http://www.dea.gov/diversion/pubs/manuals/pharm2/index.htm>