VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 5, 2002
Fifth Floor
Conference Room 2

Department of Health Professions
6606 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: The meeting of the Virginia Board of Pharmacy was called to order at 9:14 a.m.

PRESIDING: Michael C. Maloney

MEMBERS PRESENT:
Sonny Currin
Adina C. Krum
Michael J. Ayotte
Mark A. Oley
John G. Selph
Mark A. Szalwinski
William S. Tiffany

MEMBERS ABSENT: Jackson Ward

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Howard M. Casway, Assistant Attorney General
Elaine Yeatts, Senior Regulatory Analyst
Heather L. Womack, Administrative Assistant

QUORUM: With eight members of the Board present, a quorum was established.

Vernon Clement arrived at 9:45 a.m.

APPROVAL OF AGENDA: Mr. Maloney amended the agenda to include a request from Robert A. Nebiker, Director for the Department of Health Professions, to address the Board concerning the prescription monitoring program. The agenda was approved as amended.

PUBLIC COMMENTS: No public comments were received at this time.

APPROVAL OF MINUTES: Mr. Maloney called for changes or corrections to the minutes of April 29, 2002. Hearing no changes, the minutes were approved as presented.

ADOPTION OF The Board discussed the proposed draft emergency regulations to

EMERGENCY REGULATIONS:

implement chapters 411, 632, 666, 707, and 740 of the Virginia Acts of Assembly- 2002 session. Mr. Currin moved, and the Board voted unanimously to adopt the emergency regulations as presented. (Attachment 1)

ADOPTION OF DRAFT LEGISLATIVE PROPOSALS:

Ms. Russell reviewed with the Board three draft legislative proposals for approval. Mr. Ayotte moved, and the Board voted unanimously to approve the exposure draft of legislative proposal PHA-1 related to the waiver of laws and regulations in the event of an occurrence where the Governor declares a disaster or state of emergency. (Attachment 2)

PHA-3 was drafted by staff at the request of the regulation committee to remove any barriers in statute to moving toward a biennial renewal system rather than annual. If passed, the Board would need to immediately promulgate rules establishing a renewal schedule. Because of the significant fee increases and the lack of any evidence that the majority of licensees would prefer something other than an annual renewal would be more efficient, Ms. Russell recommended that PHA-3 be deferred at this time. Mr. Tiffany moved, and the motion was carried by a 6 to 3 hand count vote not to send this proposal forward, and that staff survey its licensees to determine whether a biennial renewal would be preferred.

ADDRESS BY ROBERT A. NEBIKER, DIRECTOR, DEPARTMENT OF HEALTH PROFESSIONS:

Mr. Nebiker addressed the Board concerning implementing a prescription monitoring program in State Health Planning Region III (Southwest Virginia) as required by statute. He stated that federal funds may be available to assist in the implementation of a prescription monitoring program in the Commonwealth, as well as grants from other sources. The program would entail semi-monthly or monthly reports from pharmacies, and would only monitor Schedule II prescriptions. Mr. Nebiker also stated that only a limited number of people would have access to the program, such as the Board investigators, designated special agents of the state police, and prescribers upon receiving a patient's written consent.

Mr. Nebiker also reviewed Department Directive 4.67, Agency Standards for Case Resolution. Time standards have been developed to facilitate timely resolution of disciplinary cases, and reports will be provided quarterly that compare actual performance to the standard.

ADOPTION OF DRAFT LEGISLATIVE PROPOSALS CONTINUED:

The Board continued the discussion of legislative proposals. PHA-2 was drafted by staff at the request of the Regulation Committee for regulating compounding by pharmacies. Mr. Szalwinski stated concern that medical practitioners who compounded should be held

to the same standard as pharmacists. Mr. Ayotte moved, and the Board voted unanimously to adopt PHA-2 for dissemination for comment with staff revisions to include practitioners in the standard.(Attachment 3)

CONTINUATION OF DISCUSSION ON ELECTRONIC SIGNATURES:

As continued from the previous agenda, Mr. Casway discussed electronic signatures and electronic transmission. Mr. Casway stated that he has reviewed other law related to electronic signatures and did not feel that the other law provided any definitive guidance with respect to prescriptions. He stated that it appeared an "electronic signature" is part of an electronic transmission, and if the prescription is not transmitted electronically, for example, is printed out, then the "electronic" signature is no longer valid. He stated that in the absence of specific language in the statute, the Board could interpret the statute to determine what constitutes an electronic signature. The Board agreed to refer this matter to a subcommittee to research electronic transmission and signatures further, with guidance from Board counsel. The Chair approved Mr. Ayotte, Mr. Currin, Mr. Selph, and Mr. Szalwinski to review this matter.

PLANS FOR CE AUDITS:

Samuel Johnson, Deputy Director for the Enforcement Division, discussed with the Board future plans for random CE audits instead of CE checks during routine pharmacy inspections. Mr. Johnson stated that the Board of Pharmacy could use the continuing education audit plan of the Board of Nursing Home Administrators as a template to develop its own audit plan. The Board agreed unanimously for Mr. Johnson and staff to provide an explicit CE audit plan at the next meeting in August.

REPORT ON BOARD OF HEALTH PROFESSIONS:

Ms. Russell discussed with the Board the report from the Board of Health Professions. Ms. Russell stated that the Board of Medicine has completed a statistical analysis of disciplinary actions that were taken from previous hearings, and is using those actions and data as a reference tool for future disciplinary sanctions. The Board of Health Professions is offering to extend this analysis next to the Boards of Pharmacy and Dentistry. Neal Kauder of Visual Research, Inc. will be conducting the analysis for each Board. The Board agreed to this process being conducted.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Russell distributed the NABP report discussing the adopted resolutions from the NABP 98th annual meeting. Ms. Russell stated that there is a possibility that the NABP 2005 annual meeting may be held in Virginia. The Board was also reminded that the District II meeting is being held in Virginia in the fall of 2003. Mr. Currin and Mr. Ayotte will be coordinating the conference for the Board.

APPROVAL OF DISCIPLINARY ACTIONS:

The Board reviewed the list of disciplinary actions from April 2002 through May 2002. Mr. Ayotte moved, and the Board voted unanimously to approve the list of disciplinary actions from April 2002 thru May 2002. (Attachment 4)

NEW BUSINESS:

Michael J. Ayotte addressed the Board with his concerns on the OxyContin robberies occurring in Virginia and other states. Mr. Ayotte stated that the Drug Enforcement Administration might ask for the Board's support to allow alternate delivery systems for OxyContin. Mr. Ayotte cited a central fill pharmacy with the drugs being directly sent to the patients as an example.

Mr. Ayotte publicly thanked Mr. Tiffany for all the service he has provided to the Board during both of his terms. Mr. Tiffany's second term on the Board of Pharmacy expires June 30, 2002 and he is not eligible for reappointment. Mr. Ayotte also thanked the other members, whose terms expire but who are eligible for reappointment, for their services to the Board.

CONSENT ORDERS:

Closed Session:

Mr. Currin moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A) (15) of the Code of Virginia for the purpose of deliberation to reach a decision on consent orders. Additionally, he moved that Scotti Russell, Ralph Orr, Howard Casway and Heather Womack attend the closed session because their presence is deemed necessary and will aid the Board in its deliberations.

Reconvene:

Mr. Currin moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Approval:

Mr. Selph moved, and the Board voted unanimously to approve the consent orders for Giant of Maryland and Amit Shah.

ADJOURN:

With all business concluded, the meeting adjourned at 12:30 p.m.

Heather L. Womack, Administrative Assistant

Elizabeth Scott Russell
Executive Director

Sonny Currin, Vice-Chairman

Date:

18 VAC 110-20-75. Registration for voluntary practice by out-of-state licenses.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to §54.1-3301 (12) under the auspices of a publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world shall:

1. File an application for registration on a form provided by the board at least 30 days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of § 54.1-3301 (12) of the Code of Virginia.

18 VAC 110-20-240. Manner of maintaining records, prescriptions, inventory records.

A. Each pharmacy shall maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.

3. All records of Schedule II through V drugs shall be maintained at the same location as the stock of drugs to which the records pertain except that records maintained in an off-site data base shall be retrieved and made available for inspection or audit within 48 hours of a request by the Board or an authorized agent.

4. In the event that an inventory is taken as the result of a theft of drugs pursuant to § 54.1-3404 of the Drug Control Act, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date.

5. All inventories required by § 54.1-3404 shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

6. All records required by this section shall be filed chronologically.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart Orders.

1. A chart order written for a patient in a hospital or long term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 (A) of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard-copy prescription for those patients listed in subdivision 1 of this subsection.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a chart order contains an order for a Schedule II drug and an order for a drug in another schedule, the order must be filed with records of Schedule II drugs and a copy of the order placed in the file for other schedules.

18 VAC 100-20-255. Other Dispensing Records

Pursuant to §54.1-3412, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

18 VAC 110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 (B), in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions which are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent if required by law for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18 VAC 110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to such a practitioner or other authorized person provided there is written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent if required by law for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in accordance with 18 VAC 110-20-710.

18 VAC 110-20-320. Refilling of Schedule III through VI prescriptions.

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with § 54.1-3412 and 18 VAC 110-20-255, initialed and dated by the

pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

   a. Each partial dispensing is recorded in the same manner as a refilling;

   b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

   c. No dispensing occurs after six months after the date on which the prescription order was issued.

B. A prescription for a drug listed in Schedule VI shall be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in § 54.1-3410 C or subdivision § 54.1-3411 of the Code of Virginia.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than two years after the date on which it was issued.

C. As an alternative to all manual record-keeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18 VAC 110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription ~~for~~ drugs dispensed.

D. Authorized refills of all prescription drugs may only be dispensed in reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment.

18 VAC 110-20-400. Returning of drugs and devices.

A. Drugs ~~or devices~~ may be accepted for return or exchange by any pharmacist or pharmacy for resale ~~after such drugs and devices have been taken from the premises where sold, distributed, or dispensed provided such drug or devices are in the manufacturer's original sealed containers or in unit dose container which meets the U.S.P.-N.F. Class A or Class B container requirement and provided such return or exchange is consistent with federal law and regulation.~~ in accordance with the provisions of §54.1-3411.1. Devices may be accepted for return or exchange provided the device is in manufacturer's original sealed packaging.

B. Any pharmacy accepting drugs returned from nursing homes for the purpose of re-dispensing to the indigent, free of charge, shall maintain a copy of a written agreement with the nursing home in accordance with §54.1-3411.1 (B) and a current policy and procedure manual describing the following:

1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;

2. Procedure for determining the suitability and integrity of drugs for re-dispensing to include assurance that the drugs have been stored according to official compendial standards; and

3. Procedure for assigning a beyond-use date on re-dispensed drugs.

~~**18 VAC 110-20-430. Chart order.**~~

~~A chart order for a drug to be dispensed for administration to an in-patient in a hospital shall be exempt from the requirement of including all elements of a prescription as set forth in § 54.1-3408 and § 54.1-3410 of the Code of Virginia. A hospital pharmacy policy and procedures manual shall set forth the minimum requirements for chart orders consistent with federal and state law.~~

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.

The pharmacy serving a long-term care facility shall:

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

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

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

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

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

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

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

   a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for re-dispensing to the indigent if authorized by § 54.1-3411.1 and 18 VAC 110-20-400, or destroyed by appropriate means in compliance with any applicable local, state, and federal laws and regulations.

   b. Drug destruction at the pharmacy shall be witnessed by the pharmacist-in-charge and by another pharmacy employee. Drug destruction at the facility shall be witnessed by the Director of Nursing or, if there is no Director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

   c. A complete and accurate record of the drugs returned and/or destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the

destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. All destruction of the drugs shall be done within 30 days of the time the drug was discontinued.

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

9. Ensure that a monthly review of a drug therapy by a pharmacist is conducted for each patient in long term care facilities except those licensed under Title 63-1 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18 VAC 110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

A. Any practitioner of medicine or osteopathy who provides controlled substances, which have been donated pursuant to §54.1-3301 (11) of the Code of Virginia shall apply for a controlled substances registration and inform the board of all sources of the donated drugs for this purpose on a form provided by the board.

B. A practitioner shall comply with the storage and security requirements set forth in 18 VAC 110-20-710. A practitioner shall maintain and comply with a written procedure for at least monthly inventory reviews for the removal of expired drugs.

C. A practitioner shall package any dispensed drugs in accordance with the provisions of §§ 54.1-3426 and 54.1-3427 of the Code of Virginia and sections 18 VAC 110-20-340 and 18 VAC 110-20-350.

D. A practitioner shall label any dispensed drugs in accordance with the provisions of §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and section 18 VAC 110-20-330 to include the free clinic name and address, name of the prescriber, patient name and address, date of dispensing, drug name to include the generic name if the drug has a single active ingredient, drug strength if applicable, quantity, and directions for use.

E. A practitioner shall comply with all recordkeeping requirements of § 54.1-3404 of the Code of Virginia and shall also maintain a chronological record of all Schedule II-VI drugs dispensed showing patient name and address, date of dispensing, drug name, strength, and quantity dispensed, and name or initials of the dispensing practitioner.

F. A practitioner under this section may enter into a contract or written agreement with a pharmacy whereby the pharmacy maintains all or part of the donated stock in the prescription department segregated from its regular inventory, dispenses the prescription pursuant to a written prescription by a prescriber at the free clinic, and delivers the dispensed prescription to the free clinic for pick up by the patient in accordance with subsection C of 18 VAC 110-20-275.

Department of Health Professions
2003 Session of the General Assembly

DRAFT DHP – PHA#1

A bill to enact § 54.1-3307.3 of the Code of Virginia pertaining to authority of the Board of Pharmacy to waive requirements of this chapter, Chapter 34 of Title 54.1, and 18 VAC 110-20-10 et seq. in order to permit the provision of drugs, devices, and pharmacy services to the public in the event of an occurrence where the Governor has declared a disaster or a state of emergency.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3307.3 of the *Code of Virginia* is enacted as follows:

In the event of an occurrence which the Governor of Virginia has declared a disaster or a state of emergency, and where it is necessary to permit the provision of needed drugs, devices, and pharmacy services to the citizens of the Commonwealth, the Board of Pharmacy may waive applicable requirements of this chapter, Chapter 34 of Title 54.1, and of 18 VAC 110-20-10 et seq. as determined by the Board.

Department of Health Professions
2003 Session of the General Assembly

DRAFT DHP-PHA-#2

A bill to amend and reenact §54.1-3401, repeal § 54.1-3402, and to enact §§ 54.1-34 and 54.1-34 of the *Code of Virginia* to remove obsolete language and update pharmacy law consistent with current practice which will establish parameters in pharmacy compounding which will further distinguish between pharmacy "compounding" and "manufacturing" and which will establish parameters which will allow pharmacies, consistent with federal law, to wholesale distribute small quantities of drugs to legitimate purchasers without being licensed as a wholesale distributor.

Be in enacted by the General Assembly:

1. That §54.1-3401 is amended and reenacted, § 54.1-3402 of the *Code of Virginia* is repealed, and §§ 54.1-3435.02 and 54.1-3437.01 of the *Code of Virginia* are enacted as follows:

§ 54.1-3401. Definitions.
As used in this chapter, unless the context requires a different meaning:
"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.
"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.
"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth.
"Animal" means any nonhuman animate being endowed with the power of voluntary action.
"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.
"Board" means the Board of Pharmacy.
"Change of ownership" of an existing entity permitted, registered or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of fifty percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.
~~"Compound" means the taking of two or more ingredients and fabricating them into a single preparation, usually referred to as a dosage form.~~

"Compounding means the preparation, mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to or in expectation, based on observed prescribing patterns, of a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, (ii) by a practitioner of medicine as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.1 or Title 4.1.

"DEA" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" means an unlicensed individual who, under the supervision of a licensed practitioner of medicine or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; or (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii) or (iii). "Drug" does not include devices or their components, parts or accessories.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order, which is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than twelve percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and

which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Label" means a display of written, printed or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, ~~compounding~~, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include ~~the preparing, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to his administering or dispensing of a controlled substance or marijuana in the course of his professional practice, or by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale~~ compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than twelve percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-13.19, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means: (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and

effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.
"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.
"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.
"Official written order" means an order written on a form provided for that purpose by the United States Drug Enforcement Administration, under any laws of the United States making provision therefore, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.
"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.) of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.
"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.
"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.
"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.
"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.
"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.
"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.
"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian or other practitioner, authorized by law to prescribe and administer such drugs or medical supplies.
"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the federal Food, Drug, and Cosmetic Act.
"Production" or "produce" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance or marijuana.
"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and

applicable federal law. However, this definition shall not include a drug which is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug which may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) of this title and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 of this title unless the context requires a different meaning.

§ 54.1-3402. ~~Proprietor of pharmacy exempted.~~ Repealed.

~~This article shall not be construed to require the proprietor of a pharmacy to register as a manufacturer or distributor if the products manufactured or purchased are labeled under the name of the pharmacy and dispensed within the premises and not sold for distribution and resale outside the premises.~~

§ 54.1-3410.2. Compounding.

A. A pharmacist may engage in compounding of drug products for the exclusive use of the practice location where the products are compounded, provided the dispensing of such compounded product is pursuant to a valid prescription for an individual patient consistent with the provisions of § 54.1-3303.

B. Pharmacists shall label all compounded prescriptions dispensed pursuant to a prescription in accordance with this chapter and Board regulations.

C. Pharmacists may engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with the name and strength of the compounded medication or list of the active ingredients and strengths; the facility's control number; a beyond use date as determined by the pharmacist using appropriate documented criteria; and quantity. Pharmacists shall maintain compounding records in accordance with Board regulations.

D. Pharmacists shall not distribute compounded drug products to other persons or commercial entities, including distribution to pharmacies or other entities under common ownership or control for subsequent re-distribution or resale, except that a prescriber may obtain, in small quantities, compounded products to administer, but not dispense, to an individual patient in the course of his professional practice if that compounded product is not otherwise commercially available.

E. Pharmacists shall label all compounded products distributed to a prescriber for administering to his patients with the statement "For Office Use Only"; the name and strength of the compounded medication or list of the active ingredients and strengths; the facility's control number; a beyond use date as determined by the pharmacist using appropriate documented criteria; and quantity.

F. Pharmacists shall personally supervise the compounding process for accuracy and conformity to the formula of the product being prepared and shall establish and conduct quality control procedures to monitor the output of compounded drug products for uniformity and consistency.

G. Pharmacists may compound using bulk drug substances that

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; are drug substances that are components of drugs approved by the U. S. Food and Drug Administration (FDA) for use in the United States; or that are otherwise approved by FDA;
2. That are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and
3. That are accompanied by valid certificates of analysis for each bulk drug substance.

H. Pharmacists may compound using ingredients other than bulk drug substances that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding.

I. Pharmacists shall not compound in the following circumstances:

1. Using a drug product that has been withdrawn or removed from the market by FDA because such drug products or components of such drug products have been found to be unsafe or not effective;
2. Compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, which does not include where there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.
3. Compound a drug product that has been identified by FDA or Board regulation as a product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product

J. Pharmacists shall maintain compounding records of all products compounded as part of the prescription, formula record, formula book, or other log or record showing the following:

1.the date of preparation;
2. the assigned lot number;
3. the generic name(s) and the name(s) of the manufacturer(s) of the raw materials or the brand name(s) of the raw materials; the manufacturer's lot number(s) and expiration date(s) for all components except that if the original manufacturer's lot number(s) and expiration date(s) are not known, the pharmacy shall record the source of acquisition of the components;

4. a complete formula, including methodology and necessary equipment;
5. signature or initials of the pharmacist or supportive person performing the compounding;
6. signature or initials of the pharmacist responsible for supervising supportive personnel and conducting in-process and finals checks of compounded products if supportive personnel perform the compounding function;
7. the quantity in units of finished products or grams of raw materials used in compounding the product;
8. the package size and the number of units prepared;
9. documentation of performance of quality control procedures except if the compounding process involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use; and
10. the beyond use date, and the criteria used to determine this date.

Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

K. Practitioners of the healing arts who lawfully compound drugs for administering or dispensing to their own patients pursuant to § 54.1-3301, §54.1-3304, or §54.1-3304.1 of the Code of Virginia shall comply with all provisions of this section.

§ 54.1-3435.02. Permitted pharmacies exempted.

A permitted pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as a wholesale distributor consistent with federal law provided such distributions do not exceed 5% of gross annual sales of prescription drugs or provided such distributions of Schedule II-V controlled substances do not exceed 5% of total dosage units of Schedule II-V controlled substances dispensed annually.

NAME	CITY	STATE	ENTRY DATE OF CONSENT ORDER/ORDER	VIOLATION	SANCTION
Lineberry, Daniel R.	Salem	VA	April 18, 2002	failure to comply with terms and conditions of July 5, 2001 Order; as PIC, numerous inspection deficiencies	continued on indefinite probation with terms and conditions
King-Kennedy, Yvette A.	Newport News	VA	April 16, 2002	dispensing and misbranding errors	indefinite probation with terms and conditions
Lutu, Daniel K.	Springfield	VA	April 16, 2002	continuing pharmacy education violations	$750 monetary penalty & shall obtain additional c.p.e.
Miller, Michael S.	Gate City	VA	May 8, 2002	continuing pharmacy education violations	suspended indefinitely; upon submission of additional c.p.e. & $2,000 monetary penalty; stayed suspension with terms
Gilleland, John B., III	Mechanicsville	VA	May 8, 2002	petition for reinstatement	petition granted; placed on probation with terms and conditions
Odeh, Lisa H.	Fairfax	VA	March 27, 2002	as PIC, failed to notify the Board of a change in pharmacy hours; once hours changed, pharmacy closed at times which were not in accordance with stated business hours	$100 monetary penalty
Martin, Jerry W., M.D.	Washington	VA	April 16, 2002	as permitted physician, numerous inspection deficienices to include failure to provide adequate security	one unannounced inspection by the Board within the next 12 months; statement from Dr. Martin that he has read, understands and will comply with all laws and regulations
Ning, Steven Y.	Baltimore	MD	May 6, 2002	following the August 11, 2000 summary suspension of his license, he was found to have diverted Schedule II drugs for personal and unauthorized use; incompetent due to mental condition	indefinite suspension