DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR REGULATORY REVIEW

May 15, 2006
Fifth Floor
Conference Room 1

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of conducting a review of regulations was called to order at 9AM.

PRESIDING: John O. Beckner, Vice Chairman

MEMBERS PRESENT:
Michael Stredler
Leo Ross
Bobby Ison
David Kozera
Mark Oley

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst

REVIEW: The committee reviewed, with interested parties, Part I General Provisions, Part II Licensure Requirements for Pharmacists, Part III requirements for Pharmacy Technician Registration, Part IV Pharmacies, Part X Unit Dose Dispensing Systems, Part XI Pharmacy Services to Hospitals, Part XII Pharmacy Services to Long Term Care Facilities, and Part XIV Other Institutions and Facilities. An outline of public and staff comment received during the comment period was reviewed. (Attachment A). A number of issues were identified with the current regulations that will be addressed in a NOIRA. Part IV Nuclear Pharmacies was not reviewed by the committee, but staff had requested any input from the major nuclear pharmacies in the state and no problems or issues were identified.

NEXT MEETING: It was determined that another meeting would be necessary to complete the review. Parts VI, VII, VIII, and IX, and XVI still need to be reviewed. A date for this meeting was not set at this time, but will most likely take place in July.

ADJOURN: The meeting was adjourned at 4:30PM

Elizabeth Scott Russell
Executive Director

John O. Beckner, Vice Chairman

Date

Part I. General Provisions

18VAC110-20-10. Definitions.
- **long term care facility to include other facilities? (NABP rules for institutional pharmacy)**

18 VAC 110-20-15. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

18VAC110-20-20. Fees.

Part II. Licensure Requirements for Pharmacists

18VAC110-20-30. Requirements for practical experience.

18VAC110-20-40. Procedure for gaining practical experience.
- **pharmacists in military hospitals outside the US as preceptors (Tou Yang, Seoul, South Korea**

18VAC110-20-50. Curriculum and approved schools of pharmacy.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.

18VAC110-20-70. Requirements for foreign-trained applicants.
- **clarify that must pass the FPGEE before becoming an intern (staff, and clarification of statute requirements)**

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

18VAC110-20-80. Renewal and reinstatement of license.

18VAC110-20-90. Requirements for continuing education.

18VAC110-20-100. Approval of continuing education programs.

Part III. Requirements for Pharmacy Technician Registration

18VAC110-20-101. Application for registration as a pharmacy technician.

18VAC110-20-102. Criteria for approval for training programs.
- **Do we want to require any type of renewal & review to ensure program still meets requirements, i.e. qualified trainers, law updates**

18VAC110-20-103. Examination.

18VAC110-20-104. Address of record.

18VAC110-20-105. Renewal and reinstatement of registration.

- **reactivating vs. reinstatement-statute says 15 hours for each year for reactivating while we have a 60 hour cap on reinstatement. need to change statute or reg.**

18VAC110-20-106. Requirements for continued competency.

Part IV. Pharmacies

18VAC110-20-110. Pharmacy permits generally.
not be allowed to operate from a private residence or dwelling (staff)

18VAC110-20-111. Pharmacy technicians.

- **requirement for pharmacy to maintain start date & completion date for tech in training**
- **requirement for techs to post registrations**

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

- **add free clinic guidance doc**
- **add mobile van guidance doc**
- **look at allowing a community pharmacy serving free clinic to get a second permit**

18VAC110-20-121. Innovative program approval.

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

18VAC110-20-135. Change of hours in an existing pharmacy.

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

18VAC110-20-150. Physical standards for all pharmacies.

18VAC110-20-160. Sanitary conditions.

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

18VAC110-20-180. Security system.

- **put effective dates in #5 & 6 (11/4/1993)**

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

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

- **rules for automated will call devices (current pilot)**
- **storage of will-call, confusion as to whether they have to be in Rx Dept alarmed after hours, reach over a counter and access them (staff)**

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

Part V. Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

18VAC110-20-230. Qualification as a nuclear pharmacist.

Part VI. Drug Inventory And Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

- **require a perpetual inventory for CII?**

18VAC110-20-250. Automated data processing records of prescriptions.

18VAC110-20-255. Other dispensing records.

18VAC110-20-260. [Repealed]

Part VII. Prescription Order And Dispensing Standards

- **require alternative language labeling/counseling/med guides?**

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

18VAC110-20-275. Delivery of dispensed prescriptions.

- **require that manual/contract be maintained at both pharmacy and ADS**
- **look at "informing and obtaining consent" in light of CSB patients**

18VAC110-20-276. Central or remote processing.

18VAC110-20-280. Transmission of a prescription order by facsimile machine.

- **faxing by a patient for information purposes (particularly compounded) for Schedule VI drugs (VPhA)**
- **clarify that hospice can be home hospice which is why we have the requirement for the MD to denote that this is a hospice patient. Pharmacist would know if LTCF or home infusion**
- **need to change "nursing home" to LTCF**

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

- **change definition of agent to 3408.03C not D**

18VAC110-20-290. Dispensing of Schedule II drugs.

18VAC110-20-300. [Repealed]

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.

- **any clarification on CVI refilling needed**

18VAC110-20-321. Compounding.

Part VIII. Labeling and Packaging Standards for Prescriptions

18VAC110-20-330. Labeling of prescription as to content and quantity.

18VAC110-20-340. Packaging standards for dispensed prescriptions.

18VAC110-20-350. Special packaging.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

Part IX. Standards for Prescription Transactions

18VAC110-20-360. Issuing a copy of a prescription that can be refilled.

18VAC110-20-370. (Repealed)

18VAC110-20-380. (Repealed)

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

18VAC110-20-395. Purchase of drugs.

18VAC110-20-400. Returning of drugs and devices.

18VAC110-0-410. Permitted physician licensed by the board.

18VAC110-20-411 through 18VAC110-20-416. (Repealed).

18VAC110-20-417 to 18VAC110-20-419. [Reserved]

Part X. Unit Dose Dispensing Systems

18VAC110-20-420. Unit dose dispensing system.
- **A2 may be outdated due to faxing rules, maybe not needed now**

18VAC110-20-425. Robotic pharmacy systems.

Part XI. Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.
- **quantity or duration of order?**

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

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.
- **pharmacist required to check before leaving the pharmacy (staff)**

18VAC110-20-470. Emergency room.

18VAC110-20-480. (Repealed)

18VAC110-20-490. Automated devices for dispensing and administration of drugs.
- **for 490 (1) track the language in 555 (5) related to requiring a pharmacist to check delivery orders before they leave the pharmacy (staff)**
- **maintaining record of filling for CVI not addressed**

18VAC110-20-500. Licensed emergency medical services agencies program.
- **pharmacist required to check before sealing (staff)**
- **some ability to do 1:1 exchange without having to have the CSR (various, staff)**
- **ability to have fluids outside the box (various, staff)**

18VAC110-20-510. Identification for medical intern or resident prescription form in hospitals.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

18VAC110-20-520. Drugs in long-term care facilities.
- **needs to be moved into Part XII (staff)**
- **allow stocking of OTC meds (Beverley Group)**

Part XII. Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.
- **limit the number of reviews that may be done by one pharmacist in a day-recommendation not to exceed 75 patient reviews per day (Empsy Munden)**
- **need clarification for quantity or duration of order**

18VAC110-20-540. Emergency drug kit.

18VAC110-20-550. Stat-drug box.
- **change language to allow nurse in assisted living to access even if use med aides (numerous requests including Neighborcare, Virginia Association of Nonprofit Homes for the Aging (VANHA), and Virginia Health Care Association)**

18VAC110-20-555. Use of automated dispensing devices.
- **maintain record of filling CVI?**

18VAC110-20-560. Floor stock.

Part XIII. Other Institutions and Facilities

18VAC110-20-570. Drugs in infirmaries/first aid rooms.

18VAC110-20-580. Humane societies and animal shelters.

18VAC110-20-590. Drugs in correctional institutions.

- **allow the use of samples in correctional centers (Colton Hand-pilot)**

Part XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600. Excluded substances.

18VAC110-20-610. Exempted chemical preparations.

18VAC110-20-620. Exempted prescription products.

18VAC110-20-621. Exempted anabolic steroid products.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

Part XV. Manufacturers, Wholesale Distributors, Warehousers, and Medical Equipment Suppliers

18VAC110-20-630. Licenses and permits generally. (already been changes -below- as a result of wholesale distributor regs.)

18VAC110-20-630. ~~Licenses and permits generally.~~ [~~(Repealed)~~ Issuance of a permit as a medical equipment supplier.
~~A license or permit shall not be issued to any manufacturer, wholesale distributor, warehouser, or medical equipment supplier to operate from a private dwelling, unless a separate business entrance is provided, and the place of business is open for inspection at all times during normal business hours. The applicant shall comply with all other federal, state and local laws and ordinances before any license or permit is issued.~~

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit, or for acquisition of an existing medical equipment supplier.

B. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

C. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.]

18VAC110-20-680. Medical equipment suppliers.

Part XVI. Controlled Substances Registration for Other Persons or Entities

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

- **add the requirement for inspection prior to issuance, and require that on any change of location of drug stock or remodeling have to make application and be inspected. (staff)**
- **include 14 day requirement and drugs may not be stocked until approved-track 140C**

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

- **change in responsible party-have to send in old registration?**

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

18VAC110-20-720. Requirements for recordkeeping.

18VAC110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.