COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting
Periodic Regulatory Review

November 3, 2015

1PM

TOPIC	PAGES

Call to Order: Ellen Shinaberry, Committee Chairman

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment

Agenda Items

- Issuance of Controlled Substance Registrations to Multiple Medical Clinics Located within a Medical Office Building with Same Ownership
  - Excerpt from September 29, 2015 Full Board Meeting Draft Minutes 1
  - Excerpt from September 29, 2015 Full Board Meeting Agenda Packet 2-8
- Review Parts I-IV and XIII – XVII of *Regulations Governing the Practice of Pharmacy,* chapter 20 9-12
  - Entire regulation packet available at http://www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm

Adjourn

with respect to recalled product.

MOTION:

The board voted unanimously to amend the draft guidance document by adding at the end "If the lot number for the drugs removed from the sealed individual doses is not known, then the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with Regulation 18VAC110-20-210." and adopt the guidance document as amended. (motion by S. Elliott, second by M. Elliott).

- Request for Guidance on Issuance of Controlled Substance Registrations to Multiple Medical Clinics Located within a Medical Office Building with Same Ownership

Mr. Saenz recused himself from the discussion on this subject as the issue directly relates to his employer.

Ms. Juran explained that historically the board has issued a controlled substances registration (CSR) to each office practice or department since the drugs stored within that practice or department are typically used exclusively by that office or department. Additionally, while not directly prohibited in law or regulation, the board has informally advised against a supervising practitioner and responsible party serving on multiple CSRs or providing oversight for a stock of drugs that they are not directly accessing or overseeing.

DEA recently indicated it will consider issuing a single DEA registration to a medical office building when the medical practices have the same owner. Therefore, staff requested guidance for how CSRs should be issued.

ACTION ITEM:

The board requested that staff survey other states to determine if they are issuing a single controlled substances registration to a medical office building with multiple practices located within the building operating under the same ownership and referred the issue to the Regulation Committee for further consideration. (motion by Shinaberry, second by Allen)

ELECTION OF VICE-CHAIRMAN:

Because Ms. Munden was not reappointed for a second term to the board, Ms. Warriner, who was elected vice-chairman at the June full board meeting, recently assumed the role as chairman and therefore, the board was required to elect a new vice-chairman.

MOTION:

The board voted unanimously to elect Ms. Thornberry as vice-chairman for the term of September 29, 2015 through June 30, 2016. (motion by Shinaberry, second by Logan)

- Dates for 2016 Full Board Meetings and Tentative Regulation Committee Meetings

The following dates were chosen for full board meetings in 2016: March 29, June 14, September 7, and December 12. The following dates were chosen for tentative Regulation Committee Meetings in 2016: May 26 and November 29.

REPORTS:

- Chairman's Report

Ms. Warriner announced her appointments to the standing committees on

Request for Guidance regarding Issuance of Controlled Substances Registrations to Multiple Medical Clinics located within a Medical Office Building

Staff Note: Large medical clinics with multiple practitioners treating patients often apply for a controlled substances registration (CSR) and DEA registration in order to possess a shared stock of drugs under the facility's name as opposed to individual physician's stocking their own drugs. These clinics usually represent various types of practice, e.g., pediatric primary care, maternal and fetal medicine, pediatric outpatient rehabilitation services, teen and young adult health center, outpatient surgery, clinical trials, etc. and are often located within a single medical office building.

Pursuant to §54.1-3423 D, the board has historically issued a CSR to each office practice or department since the drugs stored within that practice or department are typically used exclusively by that office or department. Additionally, the board has required a pharmacist or prescriber to serve as the supervising practitioner on the CSR application per Regulation 18VAC110-20-700 and a responsible party (usually a nurse directly accessing meds daily and responsible for recordkeeping) who is authorized by law to administer drugs.

DEA has recently indicated it will consider issuing a single DEA registration to a medical office building when the medical practices have the same owner. Staff is requesting guidance on whether it should approve a single CSR for a medical office building when the medical practices have the same owner.

Included in the agenda packet:

- Relevant law and regulations

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research with controlled substances in Schedules II through VI. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase,

possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter.

F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.

G. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

H. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

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.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are

being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

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

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB or BHA as authorized in § 54.1-3420.2 of the Code

of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

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

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking which meets the following conditions:

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

2. The installation and device shall be based on accepted alarm industry standards.

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

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, and teaching institutions possessing only Schedule VI drug.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of §54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, 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. All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in §54.1-3404 G of the Code of Virginia.

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

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TABLE OF CONTENTS

10