COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Tentative Agenda of Public Hearing and Full Board Meeting

June 18, 2013

9:00AM

Call for Public Comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

DHP Director's Report: Dianne Reynolds-Cane, M.D.

Legislation: Elaine Yeatts

- 2014 Legislative Proposals 50
  - Scheduling bill – lorcaserin 51-60
  - Rescheduling bill – tramadol 61-66
  - Authorization to license facilities of practitioner of the healing arts to sell controlled substances 67
  - Authorization for health regulatory board to take additional actions of those summarily restricted or suspended 68
  - Requirement for wholesale distributors to notify Board when ceasing distribution to dispenser 69

Regulatory Actions: Elaine Yeatts

- Regulatory Update 70

Miscellaneous: Caroline D. Juran

- NABP presentation regarding Verified Pharmacy Program - Josh Bolin, Government Affairs Director 71-72
- Adoption of amended Guidance Document 110-38, Nonresident Pharmacies to Submit Current Inspection Report 73-74
- Report on Ad Hoc Committee on Compounding and adoption of amended Guidance Document 110-36 - Jody H. Allen, Committee Chairman 75-83
- Update on review of nonresident pharmacy compounding surveys
  Adoption of proposed Sanctioning Reference Points Pharmacist Worksheet - Neal Kauder, Research Associate, Visual Research, Inc. 84-86

Reports:

- Chairman's Report
- Report on Board of Health Professions – Robert M. Rhodes
- Report on Licensure Program – J. Samuel Johnson, Jr. Handou
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handou
- Executive Director's Report - Caroline D. Juran

Election of Officers – Chairman and Vice-Chairman

New Business:

Consideration of consent orders (if any)

Adjourn

****The Board will have a working lunch at approximately 12pm.**

****Immediately following adjournment of the meeting, a panel will be convened for formal hearings.**

Proposed Regulations – Comment Period from 6/3/13 to 8/2/13

BOARD OF PHARMACY

Amendments to address on-hold prescriptions

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

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

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor

future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C;

and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

Part VI

Drug Inventory and Records

18VAC110-20-240. 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. Each pharmacy shall maintain a

perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

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 executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. 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 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.

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

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 or by date of initial entry into the automated

data processing system in compliance with 18VAC110-20-250, if such a system is employed by the pharmacy.

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 single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

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

A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:

1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:

a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.

b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.

c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.

2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.

3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.

4. ~~Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system.~~ Documentation indicating that the information entered into the computer system is correct for each on-hold prescription or each prescription that is dispensed shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data or data entry of an on-hold prescription, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription or verified the accuracy of the data entry. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).

If a bound log book, or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information and data entry of on-hold prescriptions entered into the computer that day has been reviewed by him and is correct as shown.

B. Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) and any data entry of on-hold prescriptions. ~~such~~ Such printout shall be provided within 48 hours of a request of an authorized agent.

Part VII

Prescription Order and Dispensing Standards

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

A. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation.

D. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

E. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

F. An on-hold prescription shall be entered into the automated data processing system, if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act. If an on-hold prescription is returned to a patient prior to the

initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

Proposed Regulations – Comment Period from 6/3/13 to 8/2/13

BOARD OF PHARMACY
Modifications to requirements for automated dispensing devices

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. ~~The following conditions shall apply:~~

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometic identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

~~3.~~1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, ~~dose to be administered,~~ date and time of withdrawal from the device, and

identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports.

A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping

~~4.~~2. The PIC or his designee shall conduct at least a monthly audit to review distribution ~~and administration~~ of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. ~~A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act~~ If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the

audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review administration of Schedule II through V drugs from each automated dispensing device as follows:

~~c.~~a. The audit shall include a review of ~~a sample of~~ administration records from each device per month for possible diversion by fraudulent charting. ~~A sample~~ The review shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

~~d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.~~

~~e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.~~

~~f.~~b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

~~5. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.~~

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections.

~~6.~~ Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

~~7. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.~~

~~8. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.~~

~~9.~~1. All records required by this section shall ~~be filed in chronological order from date of issue and~~ maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except: ~~a. Manual~~ manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made

available for inspection or audit within 48 hours of a request by the board or an authorized agent.

~~b.~~2. Distribution and delivery records and required ~~signatures~~ initials may be generated or maintained electronically provided:

~~(1)~~a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

~~(2)~~b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

~~(3)~~c. The system used is capable of producing a hard-copy printout of the records upon request.

~~c.~~3. Schedule II-V distribution and delivery records may ~~only~~ also be stored offsite or electronically ~~as described in subdivisions 9 a and b of this section~~ in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

~~d.~~4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, March 6, 2013

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 1:10 p.m., on March 6, 2013, to consider the summary restriction of the license of Richard B. Rice, Jr., to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Dinny Li
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Howard Casway, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Nan Dunaway, DHP Pharmacy Inspector
Vicki Garrison, DHP Pharmacy Inspector

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

RICHARD B. RICE, JR.
License No. 0202 011551

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Ms. Shinaberry and duly seconded by Ms. Stelly, the Board voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia ("Code"),

for the purpose of deliberation to reach a decision in the matter of Richard B. Rice, Jr. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Adams and duly seconded by Ms. Shinaberry, the Board unanimously voted 6-0 that, with the evidence presented, the practice as a pharmacist by Richard B. Rice poses a substantial danger to the public; and therefore, said license to practice pharmacy in the Commonwealth of Virginia be and hereby is Restricted.

Upon a motion by Mr. Adams and seconded by Ms. Stelly, the Board voted that a Consent Order for a stay of the restriction with certain terms and conditions be offered to Mr. Rice.

ADJOURN: With all business concluded, the meeting adjourned at 2:50 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Friday, March 8, 2013
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	Jody H. Allen, Committee Chair
MEMBERS PRESENT:	Robert M. Rhodes, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
LOLA M. COTTRELL Registration No. 0230-002851	Lola M. Cottrell did not appear at the informal conference, and the committee chose to proceed in her absence as the notice was mailed to Ms. Cottrell's legal address of record. The Committee discussed the allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the December 11, 2012, Notice.
Closed Meeting:	Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Lola M. Cottrell. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Cottrell a Consent Order for the indefinite suspension of her pharmacy technician registration for not less than one year.

LAUREN HUGHES
Registration No. 0230 020186

Lauren Hughes did not appear at the informal conference, and the Committee chose to proceed in her absence as the notice was mailed to Ms. Hughes' legal address of record. The Committee discussed the allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the February 12, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Lauren Hughes. Additionally, he moved that Cathy Reiniers-Day and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms Hughes a Consent Order to revoke her right to renew her pharmacy technician registration.

JESSICA D. JENNELL
a/k/a JESSICA H. DALTON
License No. 0202 208444

Jessica D. Jennell (Dalton) did not appear at the informal conference, and the Committee chose to proceed in her absence as the notice was mailed to Ms. Jennell's legal address of record. The committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 12, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jessica D. Jennell a/k/a Jessica H. Dalton. Additionally, he moved that Cathy Reiniers-Day and

Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Jennell (Dalton) an Order for a reprimand, a requirement that she obtain additional continuing education hours and the imposition of a $500 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Jennell (Dalton), unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Jennell (Dalton) within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 12:00 noon.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 12, 2013
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15 AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, Director, DHP
Arne Owens, Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With ten members present, a quorum was established.

APPROVAL OF AGENDA: An amended agenda was provided and approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the December 11, 2012 (Regulation Committee), December 12, 2012 (Full Board Meeting), December 18, 2012 (Special Conference Committee and Informal Conference Committee), January 14, 2013 (Telephone Conference Call), January 22, 2013 (Panel Formal Hearing), January 22, 2013 (Exam Committee), January 31, 2013 (Informal Conference Committee for Innovative (Pilot) Programs), February 1, 2013 (Ad Hoc Committee for Nonresident Pharmacies Sterile Compounding Surveys), February 4, 2013 (Telephone Conference Call), February 12, 2013 (Special Conference Committee and Informal Conference Committee) and February 25, 2013 (Telephone Conference Call).

MOTION: **The Board voted unanimously to approve the minutes as presented. (motion by Stelly, second by Munden)**

PUBLIC COMMENTS: Tim Musselman representing the Virginia Pharmacist Association (VPhA) commented that his members are requesting guidance from the Board on sterile compounding issues which may assist compounding

pharmacies and hospital pharmacies in complying with legal requirements. Specifically, he indicated there is confusion regarding the board's expectations during pharmacy inspections and the processes to be used by the pharmacist for appropriately assigning beyond use dates and performing sterility tests. He suggested that the board form a workgroup which would represent compounding pharmacies, hospitals, and prescribers.

Cal Whitehead with Whitehead Consulting, LLC introduced himself and his colleagues to the board and announced that they will be serving as lobbyists for the Virginia Society of Health-System Pharmacists.

DHP DIRECTOR'S REPORT:

Dr. Cane reported that the three bills submitted by DHP and included in the Governor's package had all passed during the General Assembly session. The bill which eliminated the Psychiatric Board has been signed into law. The second bill adds two anabolic steroids to the Drug Control Act to conform to federal scheduling, and the third bill prohibits a licensee whose license has been suspended or revoked from engaging in practice pending appeal of the board's order. Dr. Cane also stated that the upcoming National Governors Association (NGA) meeting is being held at DHP on March 25, 2013. Four subgroups were created to focus on prescription monitoring, education, law enforcement, and drug disposal. The meeting on the 25th is designed to be a working meeting for these four subgroups. Dr. Cane then provided an update regarding her trip to the Virginia Pharmacist Association midyear conference that was held on February 23, 2013 in Roanoke, Virginia. Mr. Kozera recognized Dr. Cane for a job well done in providing the Rooke Lecture at the VPhA meeting.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2013 General Assembly session that may potentially impact the board or the profession of pharmacy.

TORNADO DRILL:

The Board participated in the state-wide tornado drill from 9:45am until approximately 9:55am.

- Regulatory Update

Ms. Yeatts reviewed with the board the status report for pending regulatory actions which was provided in the board agenda packet.

- Adoption of fast-track regulations resulting from regulatory reform:

Ms. Yeatts provided the board with a handout which contained a Notice of periodic review for chapters 20, 30, 40, and 50, one public comment, and staff's recommended changes to chapter 20. She indicated that the comment period for the Notice was November 5, 2012 through December 5, 2012 and that the board received one comment on December 5, 2012 which was general in nature. She proceeded to review staff's recommended change to 18VAC110-20-20 which would assist the agency in accommodating electronic renewal notices and encourage on-time payments by clarifying that the renewal fees may be paid at any time "up to" the expiration date. Suggested changes to 18VAC110-20-40 would allow the board to accept certification of pharmacy intern hours of practical experience from an ACPE-approved school of pharmacy when a state relies on the school to certify the hours. Suggested changes to 18VAC110-20-105 would remove the requirement that a pharmacy technician provide proof of continuing education (CE) when performing a late renewal of his registration and would simply require an attestation of

having obtained the required CE. Suggested changes to 18VAC110-20-270 would incorporate guidance from Guidance Document 110-22 which addresses conflicts between 18VAC110-20-270, 18VAC110-20-276, and 18VAC110-20-515. Suggested changes to 18VAC110-20-420 eliminates possible conflict with HIPAA by requiring labeling of drug drawer or tray simply in a manner that identifies the patient and his location without violating health privacy laws. Suggested changes to 18VAC110-20-425 would expand allowances for a robotic pharmacy system to dispense drugs in bar-coded compliance packaging. Suggested changes to 18VAC110-20-710 would remove potentially burdensome alarm requirements for teaching institutions possessing only Schedule VI drugs. Ms. Yeatts indicated these changes would follow the fast-track process since they are expected to be noncontroversial. After Executive Branch review and publishing in the Register, a 30-day public comment period will begin. If ten or more members of the public object to the regulatory changes then publication of the fast-track regulation will serve as the Notice of Intended Regulatory Action (NOIRA) and the standard rulemaking process will be followed. Ms. Shinaberry requested that in the future staff provide suggested regulatory changes to the members in advance of the meeting, if possible.

MOTION:

The Board voted to adopt the proposed fast-track regulatory amendments as presented by staff and that resulted from the periodic regulatory review required by the Governor to address overly burdensome regulations. (motion by Allen, second by Shinaberry) (Warriner abstained)

A member commented that it appears to take significantly more time for inspectors to perform sterile compounding inspections given the complexity of the subject. It was questioned whether licensing fees should be increased for those pharmacies performing sterile compounding. Ms. Juran indicated she is aware that a few states have considered this approach to address concerns with rising inspection costs associated with sterile compounding.

ACTION ITEM/ MOTION:

After discussion, the Board voted unanimously that staff should collect data on how much time is spent on performing routine inspections of pharmacies performing sterile compounding to determine if there is a validated concern for rising costs directly associated with sterile compounding and research what actions other states are taking to address cost increases. (motion Ellen, second Adams)

- Revenue, Expenditures and Cash Balance Analysis:

Ms. Yeatts reviewed with the Board the Revenue, Expenditures and Cash Balance Analysis that was conducted by the agency over the 2010-2012 biennium (July 1, 2010 through June 30, 2012). It was recommended by the agency that no fee increase be taken at this time.

INTRODUCTION:

Mr. Kozera called for the introduction of Mr. Paul Dalby who is the new Deputy Director for the Enforcement Division.

MISCELLANEOUS:

- Request for special considerations from Free Clinic of Franklin County, Inc.

Ms. Juran reviewed with the board the letter included in the agenda packet from the Free Clinic of Franklin County, Inc. that expressed concern for the cost associated with paying a pharmacist to operate the pharmacy. It indicated the clinic is in an area that is medically underserved, they cannot find pharmacists to volunteer in their clinic, they pay one pharmacist to operate the clinic's pharmacy, but that the cost is impacting services that could be provide to indigent patients. The clinic requested the ability for a licensed provider (MD, PA, FNP) to directly supervise pharmacy activities under the general supervision of a pharmacist who will be onsite at least once weekly or for the pharmacy technician to begin preparing medications 1-2 hours before the pharmacist arrives to supervise and approve the medications prior to dispensing. The board discussed current allowances in place for free clinics and requested staff to outline these provisions in a letter to the free clinic. The board also expressed concerns for drug security and lack of direct pharmacist supervision in the requested options. The board then asked the public present and those representing pharmacy associations to please assist this clinic in communicating the need for volunteer pharmacists.

MOTION:

The Board voted unanimously to deny the request from the Free Clinic of Franklin County, Inc. (motion by Rhodes, second by Stelly)

- Update on Sanctioning Reference Points evaluation and revision process:

Kim Langston, Research Associate with Visual Research, presented the Sanctioning Reference Points evaluation (SRP) that was completed for the Board of Pharmacy. Confidential consent agreements (CCAs), pre-hearing consent orders (PHCOs) and pre-defined sanctions are all new to the SRP since they were not commonly used during the development of the SRP. At this time, information regarding board cases is being transferred into a new database and the types of violation have changed since the implementation of the SRP. Ms. Langston stated that the board implemented the SRP process in 2007 and has currently completed seventy-six SRPs. Ms. Langston reported that Visual Research has been conducting interviews of select board members and staff to gain feedback and recommendations for the SRP process. She offered a summary of responses from the interviews that were conducted. She recommended to the Board that pharmacy technicians have their own worksheet and it could be presented with the revised pharmacist worksheet at the June board meeting.

MOTION:

The Board voted unanimously to approve the continuation of the Sanction Reference Points evaluation being conducted by Visual Research, Inc. (motion by Shinaberry, second by Allen)

- Adoption of Guidance Document 110-18

Ms. Juran reviewed with the board a handout with suggested revisions for Guidance Document 110-18 which is entitled, "Interpretation of administer to include preparation for administration." She indicated that the third paragraph should be deleted since the allowance for administering drugs in schools is now addressed in §54.1-3408 and this guidance may potentially conflict with schools' policies. Additionally,

Ms. Yeatts reported that the issue of drug administration is more appropriately addressed by the Board of Pharmacy since it enforces the Drug Control Act and that the Board of Nursing approved the reference to them being deleted.

MOTION: **The Board voted unanimously to amend Guidance Document 110-18 as presented. (motion by Warriner, second by Adams)**

- Adoption of amended Guidance Document 110-9:

The Board reviewed staff's suggested changes to Guidance Document 110-9 which was included in the agenda packet. Regarding Major Deficiencies 22 and 23, staff had received comment from certifying companies that it is standard practice to perform a hood certification no later than the last day of the month in which the certification is due. Ms. Juran explained that she was waiting on confirmation of this information from Eric Kastango, an expert on USP standards.

MOTION: **The Board voted unanimously to adopt amended Major Deficiencies 22 and 23 in Guidance Document 110-9 as presented, have staff report its findings from the USP expert at the June board meeting, and apply the guidance retroactively to any inspections citing this violation since the December 2012 full board meeting. (motion by Stelly, seconded by Allen)**

It was suggested that the proposed changes for Major 25c and Major 26a read to say "failed" instead of "negative". The amendments for Major 34 and Minor 42 concerning records were discussed, and it was recommended that no monetary penalty for deficiencies associated with CQI requirements be imposed until a later date.

MOTION: **The Board voted unanimously to amend the following deficiencies in Guidance Document 110-9:**

- **Major 25c by replacing the word "negative" with the word "failed";**
- **Major 26a as presented with the exception of replacing the word "negative" with the word "failed";**
- **Major 35 as presented; and,**
- **Major 34 and Minor 42 as presented with the exception that a monetary penalty will not be imposed until a later time.**

(motion by Rhodes, second by Munden)

- Request from staff for guidance regarding continued actions to address sterile compounding issues:

Ms. Juran requested guidance from the Board regarding continued actions to address sterile compounding issues. Ms. Juran stated that an ad-hoc committee was formed and met February 1, 2013 to review non-resident pharmacy compounding survey responses that were sent out in December. It was discussed that the same committee should meet again to continue the review of the survey responses, and a new committee should be formed, to include representation from VPhA, VSHP, and MSV, to develop consensus language for the full board to consider in the drafting of a guidance document on sterile compounding issues. Mr. Kozera instructed board members who are interested in participating on the committee to contact Ms. Juran and that he would appoint members to the ad hoc committee.

- Request from staff for guidance regarding whether drugs provided by a physician for an infusion pump constitutes dispensing or administering:

Ms. Juran requested guidance from the Board regarding whether the act of a physician providing a patient with an infusion pump containing drug constitutes administration or dispensing of a drug. Staff has been contacted by two physician offices who are seeking clarification as to whether the physician must obtain a dispensing license when providing a patient with an infusion pump containing drug.

MOTION:

The Board voted unanimously that the act of a physician providing a patient with an infusion pump containing drug which will administer doses after leaving the physician's office constitutes dispensing and that the physician will need to obtain a license to dispense. (motion by Stelly, second by Munden)

REPORTS:

- Report on Board of Health Professions:

Mr. Rhodes gave an update regarding previous and upcoming meetings with the Board of Health Professions. He stated that the Regulatory Research Committee met on February 5, 2013 and he gave an overview and discussed the minutes of the meeting with the Board.

- Report on Licensure Program:

Mr. Johnson reported that the Board issued 843 licenses and registrations for the period of December 1, 2012 through February 28, 2013, including 85 pharmacists, 133 pharmacy interns, and 481 pharmacy technicians. Inspectors conducted 262 facility inspections including 56 routine inspections of pharmacies: 16 resulted in no deficiency, 12 with deficiencies, and 28 with deficiencies and a consent order.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of March 12, 2012; June 8, 2012; September 28, 2012; and March 8, 2012. For the final date, open cases are two at the entry stage; 55 at the investigation stage; 64 at the probable cause stage; 20 at the administrative proceedings division stage; 12 at the informal stage; six at the formal stage; and 101 at the pending closure stage.

Further, Ms. Reiniers-Day requested that the Board review the September 27, 2006, Board's guidance regarding the offering of a prehearing Consent Order associated with non-reporting to the Prescription Monitoring Program. She explained that the Guidance Document was put in place when reporting was required less frequently and the sanction was to immediately submit the reports as well as impose a $1,000 monetary penalty for each unreported period. The law has now been changed to require weekly reporting.

MOTION:

The Board voted unanimously to amend Guidance Document 110-06 to indicate that a prehearing Consent Order shall be offered with the sanction that the required reports be submitted immediately as well as impose a $250 monetary penalty for each unreported period to the

Prescription Monitoring Program. (motion by Adams; second by Allen)

- Executive Director's Reports:

Ms. Juran gave an update to the Board that the next DEA take-back event will be held April 27, 2013. The NABP annual meeting will be held May 18th through May 21st in St. Louis, MO and that Mr. Kozera, Ms. Allen, Ms. Warriner, Mr. Rhodes, Mr. Adams, Ms. Thornbury and herself were planning to attend. She reminded those attending that the deadline for the reduced hotel rate was April 27th. Ms. Juran also reported on the Healthcare Workforce Data Center forum held by Nursing, Dentistry and Pharmacy where the media and key stakeholders were invited to DHP to hear reports from recent surveys. The Board of Pharmacy reviewed reports from the 2011 pharmacy technician and pharmacist surveys. Ms. Juran stated that Mr. Kozera had recently appointed members to a new committee for the hearing of disciplinary cases related to inspection violations and continuing education audit violations. The two-member committee consists of Ms. Munden as chairman and Mr. Adams, with Ms. Warriner serving as an alternate member. The National Governors Association (NGA) meeting is being held at DHP on March 25, 2013 and it is open to the public. Ms. Juran also reviewed the expenditure report concerning the revenue for the Board of Pharmacy.

LUNCH:

The Board broke for lunch at approximately 12:45pm and presented former Board members Gill Abernathy and Brandon Yi with plaques of appreciation for their time and service to the Board of Pharmacy.

RECONVENE:

The Board reconvened at approximately 1:45pm.

CONSIDERATION OF CONSENT ORDERS:

MOTION FOR CLOSED MEETING:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Howard Casway, Sammy Johnson and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Allen, second by Warriner)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

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 a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Allen, second by Adams)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jonathan C. Spitler, Pharmacist (motion by Adams, second by Munden)

MOTION:

The Board voted unanimously to accept the Consent Order as

presented by Ms. Reiniers-Day in the matter of Jessica L. Malin, Pharmacy Technician (motion by Warriner, second by Rhodes)

ADJOURN: With all business concluded, the meeting adjourned at 2:25 pm.

David C. Kozera, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, March 12, 2013
Commonwealth Conference Center
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:30 p.m.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Heather Hurley, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Shevaun Roukous, DHP Adjudication Specialist

QUORUM: With ten (10) members of the Board present, a panel was established.

AJANI MOORE
Registration # 0230-014090

A formal hearing was held in the matter of Ajani Moore, following the summary suspension of his pharmacy technician registration on February 11, 2013, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Shevaun Roukous, DHP Adjudication Specialist.

Adam Harrell, Walgreen's District Loss Prevention Manager, and Kimberly B. Lynch, DHP Senior Investigator , testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the panel voted 10-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Ajani Moore. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Heather Hurley and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Mr. Adams, the panel voted 10-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Rhodes and duly seconded by Mr. Adams, the panel voted 10-0 that Mr. Moore's registration to practice as a pharmacy technician shall be revoked.

RUSSELL STUART GATES
License #0202-009066

Mr. Halbleib presented a Consent Order to the Board regarding Mr. Gates.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Shinaberry, the panel voted 10-0 to enter into a closed meeting pursuant to § 2.2-3711(A)(27) of the code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order for Russell Stuart Gates. Additionally, it was moved that Cathy Reiniers-Day, Caroline Juran, Heather Hurley, Howard Casway, Wayne Halbleib, Shevaun Roukous and Sammy Johnson attend the closed meeting.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the panel voted 9-1 (Mr. Rhodes voting nay) to accept the Consent Order as presented by Mr. Halbleib in the matter of Russell Stuart Gates.
Adjourn:	With all business concluded, the meeting adjourned at 4:20 p.m.

David C. Kozera, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

MINUTES OF AD HOC COMMITTEE FOR RFP OF PHARMACY TECHNICIAN EXAM

March 12, 2013
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 4:35 p.m.

PRESIDING: Robert M. Rhodes, Committee Chairman

MEMBERS PRESENT: Empsy Munden
Jody H. Allen

STAFF PRESENT: J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director

APPROVAL OF AGENDA: With no changes made to the agenda, upon a motion by Ms. Munden and duly seconded by Mr. Rhodes, the agenda was approved as presented.

The Examination Committee met to discuss proposals submitted in response to a Request for Proposal for the Virginia Pharmacy Technician Examination.

CLOSED MEETING:

Upon a motion by Ms. Munden, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(29) of the Code of Virginia, for the purpose of discussion of the award of a public contract involving the expenditure of public funds, including interviews of bidders or offerors, and discussion of the terms or scope of such contract, where discussion in an open session would adversely affect the bargaining position or negotiating strategy of the public body. Additionally, she moved that J. Samuel Johnson, Jr., and Cathy Reiniers-Day attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting.

ADJOURN: With all business concluded, the meeting adjourned at 5:20 p.m..

Robert M. Rhodes
Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, April 9, 2013
Commonwealth Conference Center
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:00 a.m.

PRESIDING: Jody H. Allen, Chair

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Sharon Davenport, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven (7) members of the board present, a panel was established.

RUSSELL T. LEDERHOUSE
License # 0202-207604

A formal hearing was held in the matter of Russell T. Lederhouse, following the summary suspension of his pharmacist license on March 1, 2013, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Vicki Garrison, DHP Pharmacy Inspector, and Nan Dunaway, DHP Pharmacy Inspector, testified on behalf of the Commonwealth. Additionally, Eric Kastango, MBA, Pharmacist and President and CEO of Clinical IQ, LLC; testified via telephone on behalf of the Commonwealth.

James Morris, Esquire, represented Mr. Lederhouse in this matter. Further, Mr. Lederhouse testified on his own behalf.

Ms. Thornbury departed at 6:40 p.m.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Warriner, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Russell T. Lederhouse. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day, Howard Casway and Sharon Davenport attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Adams and duly seconded by Ms. Stelly, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Mr. Casway.

Upon a motion by Ms. Munden and duly seconded by Mr. Adams, the panel voted 6-0 that Mr. Lederhouse's license to practice as a pharmacist shall be continued on indefinite suspension for a period of not less than one year.

Adjourn:

With all business concluded, the meeting adjourned at 9:40 p.m.

_____
Jody H. Allen, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, April 16, 2013
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director
BRONWEN A. STEBBINS License No. 0202 206762	Bronwen A. Stebbins did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Stebbins' legal address of record. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 27, 2013, Notice. Shevaun Roukous, DHP Adjudication Specialist, was present as staff for this conference.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Bronwen A. Stebbins. Additionally, she moved that Cathy Reiniers-Day and Shevaun Roukous attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Stebbins an Order with certain terms and conditions.

NOTE: Mykl D. Egan, DHP Adjudication Specialist, staffed the remaining informal conferences.

JANE P. WRIGHT
License No. 0202 010363

Jane P. Wright appeared with Hannah Lloyd, her counselor; and Sue Coleman, her supervisor, to discuss her petition for reinstatement of her pharmacist license and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 27, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jane P. Wright. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order reinstating Ms. Wright's pharmacist license once she complies with certain conditions.

TRAVIS A. HALE
License No. 0202 011551

Travis A. Hale appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 27, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Travis A. Hale. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Hale an Order imposing a reprimand.
LINDA J. ECKERT Registration No. 0230 002881	Linda A. Eckert appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the March 27, 2013, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Linda J. Eckert. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, Ms. Allen, the Committee closed this case with no violation.
RICHARD B. RICE, JR. License No. 0202 011551	Richard B. Rice appeared with Hunter W. Jamerson and Lindsey Walton, his attorneys to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 1, 2013, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Richard B. Rice. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan

attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision: Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to Mr. Rice requiring him to comply with certain terms prior to performing any sterile compounding.

ADJOURN: With all business concluded, the meeting adjourned at 6:30 p.m.

David C. Kozera, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Tuesday, April 16, 2013
Commonwealth Conference Center
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 6:30_ p.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
SOUTH RIVER COMPOUNDING PHARMACY, WEST END, INC. Permit No. 0201-004172	Richard B. Rice, Jr., Pharmacist-in-Charge, and Hunter W. Jamerson and Lindsey Walton, his attorneys, appeared on behalf of South River Compounding Pharmacy, to review allegations that South River Compounding Pharmacy, West End, Inc., may have violated certain laws and regulations governing the conduct of pharmacy as stated in the April 1, 2013, Notice.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of South River Compounding Pharmacy, West End, Inc. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to South River Compounding Pharmacy, West End, Inc., for a monetary penalty in the amount of $16,000.

(This Consent Order shall be effective upon endorsement by South River Compounding Pharmacy, West End, Inc. and the Board of the findings of fact, conclusions of law, and terms of the Order).

ADJOURN:

With all business concluded, the meeting adjourned at 7:10 p.m.

David C. Kozera
Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, April 17, 2013
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
CHRISTOPHER K. CURRIN License No. 0202 011727	Christopher K. Currin appeared with F. Carthan Currin, Jr., co-owner of RX 3, and Nathan Kottkamp, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 2, 2013, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Christopher K. Currin. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order taking no further action regarding Mr. Currin and the allegations.
ADJOURN:	With all business concluded, the meeting adjourned at 12:30 p.m.

David C. Kozera, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Wednesday, April 17, 2013
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 12:30 p.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
RX 3 Permit No. 0201-003124	Christopher K. Currin, co-owner and the pharmacist-in-charge; F. Carthan Currin, Jr., co-owner; and Nathan Kottkamp, appeared on behalf of RX 3 to review allegations that RX 3 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the April 2, 2013, Notice.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of RX 3. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law

and unanimously voted to offer a Consent Order to South River Compounding Pharmacy, West End, Inc., for a monetary penalty in the amount of $10,500.

(This Consent Order shall be effective upon endorsement by RX 3 and the Board of the findings of fact, conclusions of law, and terms of the Order).

ADJOURN: With all business concluded, the meeting adjourned at 2:15 p.m.

David C. Kozera
Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON COMPOUNDING

Monday, May 13, 2013
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of an Ad Hoc Committee on Compounding of the Board of Pharmacy was called to order at 1:15P.M.
PRESIDING:	Jody H. Allen, Committee Chairman
MEMBERS PRESENT:	David C. Kozera – Board Chairman R. Crady Adams- Board Member Empsy Munden- Board Member Ellen Shinaberry – Board Member Tim Musselman representing VPhA James Dice representing VSHP Dr. Alan Wagner representing MSV Dr. Jeff Newman representing VVMA
MEMBERS PARTICIPATING VIA TELEPHONE:	Eric Kastango, Principal-CEO, Clinical IQ, LLC
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Howard Casway, Sr. Asst. AG, Board Counsel Elaine Yeatts, Senior Policy Analyst, DHP Heather Hurley, Administrative Assistant
APPROVAL OF AGENDA:	With no changes made, the agenda was approved as presented.
OVERVIEW OF COMPOUNDING REQUIREMENTS:	Ms. Allen stated that the committee objective was to identify common areas of confusion and non-compliance with compounding requirements and recommend consensus language to the board for its consideration when adopting guidance to address the identified areas. Ms. Juran briefly identified the law and regulation within the agenda packet which requires compounding to be performed in compliance with USP-NF standards. Mr. Kastango then provided a brief overview of USP-NF requirements for sterile compounding by reviewing with everyone the slides included in the agenda packet.

DEVELOPMENT OF CONSENSUS LANGUAGE:

Ms. Allen led discussion for each of the 13 identified areas of confusion/non-compliance which was found on page 15 of the agenda packet. Various comments and input were provided by the committee participants for each of the subjects. Staff was tasked with drafting "frequently asked questions" on each subject for the committee to present to the full board for its consideration at the June 18, 2013 full board meeting. The FAQs are intended to clarify areas of confusion with sterile compounding requirements and improve compliance.

Dr. Wagner expressed concern that many pharmacies, following board inspection, were no longer willing to provide repackaged Avastin for office administration. Dr. Wagner indicated the Avastin is frequently administered for off-label uses to treat various retinal conditions, other drug treatments were cost-prohibitive, and that patients would go blind without access to the Avastin. Ms. Juran explained that pharmacists may only repackage Avastin pursuant to a patient-specific prescription. The act of repackaging Avastin for office use does not comport with the definition of "compounding" as it does not involve the "combining of two or more ingredients", but rather with "manufacture" as it involves repackaging (Va Code §54.1-3401). Because federal law also prohibits pharmacies from providing repackaged Avastin for office administration and Congress is currently reviewing proposed bills to address compounding issues, Dr. Wagner was encouraged to first address this issue on a federal level.

Dr. Newman stated that veterinarians frequently rely on compounded drugs to treat animals for which a commercial drug is not available. In treating emergent conditions, he indicated it is important for the veterinarian to have the compounded drug on-hand. Ms. Juran confirmed that §54.1-3410.2 does allow a pharmacy to provide a compounded drug to a veterinarian for office administration. Dr. Newman expressed concern that he cannot directly dispense a compounded drug to the client as §54.1-3410.2 does not allow a pharmacy to compound a drug for further distribution. While a prescription may be provided to the client to have dispensed by a pharmacy, Dr. Newman stated that often the compounded drug is needed in a timelier manner. Dr. Newman was also

encouraged to address this issue federally during current Congressional discussions of proposed bills since federal legislation would likely dictate the direction of state laws.

As time did not permit the review of the 17 draft FAQs on pages 16-18 of the agenda packet, staff volunteered to review the FAQs for completeness and accuracy prior to the June board meeting. No other areas of concern/non-compliance were identified or discussed during the meeting.

ADJOURN: With all business concluded, the meeting adjourned at 5:05P.M.

Jody H. Allen, Committee Chairman

Caroline D. Juran
Executive Director

Date

Date

Agenda Item: **DRAFT Legislative Proposals**

Enclosed:

Copies of draft bill for:

Addition of Lorcaserin to Schedule IV

Addition of Tramadol to Schedule IV

Authority for the Board to issue permits to facilities for physicians selling drugs

Authority for the Board to order a drug recall in case of a suspension or revocation of a permit or license

Requirement for wholesale distributors to notify Board when ceasing distribution to dispensers

Board Action:

Approval of legislative proposals to be distributed for comment and submitted for consideration for the 2014 General Assembly Session.

Rules and Regulations

Federal Register
Vol. 78, No. 89
Wednesday, May 8, 2013

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052–AC54

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Liquidity and Funding; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correction.

SUMMARY: The Farm Credit Administration (FCA) published a final rule in the **Federal Register** on April 18, 2013 to strengthen liquidity risk management at Farm Credit System (System) banks, improve the quality of assets in their liquidity reserves, and bolster the ability of System banks to fund their obligations and continue operations during times of economic, financial, or market adversity. This document corrects that rule by replacing a term that was inadvertently used.

DATES: *Effective Date:* This regulation will be effective 30 days after publication in the **Federal Register** during which either or both Houses of Congress are in session. We will publish a notice of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: David Lewandrowski, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA, (703) 883–4498, TTY (703) 883–4056; or Richard A. Katz, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: The FCA published a document in the **Federal Register** on April 18, 2013, (78 FR 23438) amending part 615. In FR Doc. 2013–09166, make the following corrections on two separate pages.

■ 1. Remove the term "book" and add in its place, the term "market" on page 23453, in the first column, line 18.

§ 615.5134 [Corrected]

■ 2. On page 23456, in the first column, line 4, in § 615.5134(e), remove the term "book" and add in its place, the term "market".

Dated: May 1, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–10820 Filed 5–7–13; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–369]

Schedules of Controlled Substances: Placement of Lorcaserin Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance lorcaserin, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule IV of the Controlled Substances Act (CSA). This action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: *Effective Date:* June 7, 2013.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone, (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended (hereinafter, "CSA"). The implementing regulations for these statutes are found in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause, 21 U.S.C. 812. The initial schedules of controlled substances by statute are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR Part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed . . ." Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of DEA.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of HHS and on an evaluation of all other relevant data by DEA. This action imposes the regulatory controls and criminal sanctions of Schedule IV on the manufacture, distribution, dispensing, importation, and exportation of lorcaserin and products containing lorcaserin.

Background

Lorcaserin ((*R*)–8–chloro–1–methyl–2,3,4,5–tetrahydro–1*H*–3–benzepine hydrochloride hemihydrate) is a new

[1] As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration, (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518. In addition, because the Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

chemical entity which has central nervous system hallucinogenic properties. Lorcaserin is a serotonin receptor agonist, at the $5HT_{2C}$ and $5HT_{2A}$ receptor subtypes. Lorcaserin HCl was approved by the Food and Drug Administration (FDA) on June 27, 2012, as an addition to a reduced-calorie diet and exercise, for chronic weight management and it will be marketed under the trade name BELVIQ®.

HHS and DEA Eight-Factor Analyses

On June 25, 2012, the Department of Human Health Service (HHS) provided to the Drug Enforcement Administration (DEA) a scientific and medical evaluation and scheduling recommendation entitled "Basis for the Recommendation for Control of Lorcaserin in Schedule IV of the Controlled Substances Act." Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that lorcaserin be controlled in Schedule IV of the CSA under 21 U.S.C. 812 (b).

In response, DEA conducted an eight-factor analysis of abuse potential of lorcaserin pursuant to 21 U.S.C. 811(c).

Determination to Schedule Lorcaserin

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from HHS, the Administrator of the DEA published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) entitled, "Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV" on December 19, 2012 (77 FR 75075), which proposed placement of lorcaserin into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before January 18, 2013.

Comments Received

DEA received seventy-one comments on the proposed rule to schedule lorcaserin. Commenters included individual health-care providers, national organizations, shareholders in the company which will market BELVIQ®, consultants, medical researchers, and other concerned citizens. There were 16 commenters in favor of the proposed rule and one opposed to it, with the remaining 54 commenters not taking a position.

Support of the Proposed Rule

Fifteen commenters supported controlling lorcaserin as a Schedule IV substance. Eleven commenters indicated support for controlling lorcaserin under the CSA based on the abuse potential of the substance. Most of the commenters supported the proposal to control lorcaserin as a Schedule IV substance. Because lorcaserin will be indicated as a weight loss drug, some commenters mentioned that there will be a high demand for the drug by the general public upon the drug being marketed. According to the commenters, controlling lorcaserin as a Schedule IV substance will therefore provide the necessary controls to prevent its diversion. Two commenters mentioned that weight loss drugs are needed in the United States.

DEA Response: DEA appreciates the support for this rulemaking.

Opposition to the Proposed Rule

Two commenters opposed the proposal to control lorcaserin as a Schedule IV substance. One commenter stated that lorcaserin should be controlled as a Schedule V substance, based on the commenter's stance that DEA is making assumptions of the abuse potential of lorcaserin. The commenter indicated that DEA did not include the methodology used to determine the abuse potential of lorcaserin. The other commenter stated that lorcaserin should be a non-controlled substance based on data from a published study on the abuse potential of lorcaserin in recreational polydrug users.[2]

DEA Response: DEA does not agree. The studies used to assess abuse potential of lorcaserin are widely held as the standard methods of evaluation. Clinical studies indicated that lorcaserin, similar to comparator drugs zolpidem (Schedule IV) and ketamine (Schedule III) produced significant increases on positive subjective measures (VAS for "high" and "good drug effects") as well as an increase on the VAS for "hallucinations." Lorcaserin, as well as zolpidem and ketamine, significantly increased reports of "sedation" on the subjective scale of the ARCI, compared to placebo. In a human abuse potential study, incidence of euphoria resulting from lorcaserin administration is similar to the incidence reported following zolpidem (Schedule IV) administration (13–16%) and lower than that following ketamine (Schedule III) administration (50%). The DEA did consider in its evaluation the published article [1] cited by the commenter. The data collectively suggest that lorcaserin does have sufficient abuse potential to warrant control under the CSA. HHS recommended control of lorcaserin in Schedule IV of the CSA and the DEA's placement findings support this level of control.

Requests To Control Lorcaserin in a Higher Schedule Than Schedule IV

Four commenters expressed concern that Schedule IV was not a stringent enough schedule for lorcaserin, based on it being an agonist at the $5–HT_{2A}$ receptors. These commenters suggested that lorcaserin be controlled in Schedule II or Schedule III. $5–HT_{2A}$ receptors mediate hallucinogenic properties of other drugs, such as lysergic acid diethylamide (LSD).

DEA Response: DEA believes that placement in Schedule IV of the CSA will help restrict unsafe access to lorcaserin and reduce instances of its abuse. Upon receiving from HHS a scientific and medical evaluation and a scheduling recommendation for lorcaserin, DEA also conducted its own analysis of the eight factors in accordance with 21 U.S.C. 811(b). Based on the review of HHS' evaluation and scheduling recommendation and other relevant data, DEA found that lorcaserin had a low potential for abuse relative to ketamine, a Schedule III drug, a currently accepted medical use for treatment in the United States, and that abuse of lorcaserin may lead to limited physical or psychological dependence relative to drugs in Schedule III. On the basis of these findings, lorcaserin is appropriately being controlled in Schedule IV.

Requests To Expedite the Lorcaserin Scheduling Action

There were thirty-two comments which requested that DEA expedite the scheduling action for lorcaserin. Generally, the commenters indicated that the scheduling action should be expedited due to epidemic levels of obesity in the United States and the absence of any weight loss drugs on the market with lorcaserin's novel mechanism of action. Some commenters stated that the review conducted by FDA was sufficient to justify that lorcaserin be controlled expeditiously. Of these thirty-two comments, seven comments also requested that, "in the interest of public health," DEA waive the 30-day comment or implementation period in order to make lorcaserin available immediately. One commenter stated that the scheduling action should be expedited because "based on scientific evidence that is available to date, there is no risk of this drug being addictive, and therefore abused."

From the previously mentioned thirty-two comments, eight comments

[2] Shram et al. (2011) Clin Pharmacol Ther; 89(5):683–92.

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requested that the placement of lorcaserin in Schedule IV become effective on the date of the publication of the Final Rule. One commenter requested that the implementation period be limited to two weeks instead of the standard 30 days. Generally the commenters stated that since obesity and obesity-related illnesses are occurring at epidemic levels, lorcaserin should be available to health care practitioners and patients in the immediate future. One commenter referenced other scheduling actions in which the effective date was the same as the publication date of the Final Rule as justification of doing the same for the lorcaserin. The scheduling actions referenced were zopiclone (70 FR 16935), pregabalin (70 FR 43633), and ezogabine (76 FR 77895).

DEA Response: DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with regulatory requirements for handling Schedule IV controlled substances. With regard to the comment about lack of abuse potential for lorcaserin, as mentioned in both HHS' and DEA's scientific and medical analyses, the data collectively suggest that lorcaserin does have sufficient abuse potential and though the effective dates for scheduling zopiclone, pregabalin, and ezogabine were the date of publication of their respective Final Rule, DEA does not agree that lorcaserin's effective date should be the date of publication of the Final Rule. The clinical indications of above referenced drugs are different from that of lorcaserin. DEA believes that the clinical indications for lorcaserin do not support the waiver of the 30-day period. With regard to the availability of weight-loss drugs, DEA further notes that other weight-loss drugs are currently available on the market.

Phentermine Being Combined With Lorcaserin

Eight commenters expressed concern about the probability that healthcare providers would prescribe phentermine with lorcaserin to increase weight loss results in patients.

DEA Response: Prescriptions for controlled substances, including lorcaserin, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. A determination of the validity of a prescription depends on an evaluation of the particular circumstances surrounding its issuance.

Risk Evaluations and Mitigation Strategy (REMS) Program for Lorcaserin

Three commenters stated that there should be a REMS program in place for the prescribing and dispensing of prescriptions of lorcaserin to minimize the misuse of lorcaserin. Two of these commenters also expressed concern about the effects of direct-to-consumer television advertisements of lorcaserin.

DEA Response: FDA is responsible for determining whether REMS programs should be implemented for particular drugs. Various agencies, such as FDA and the Federal Trade Commission (FTC), have a role in regulating direct-to-consumer drug advertising.

Request for a Hearing

One commenter requested a formal hearing prior to the finalization of the scheduling action for lorcaserin. The commenter expressed concern that the potential for abuse of lorcaserin is large since the indication is for the drug to be taken chronically for weight loss. The commenter requested that the hearing include "relevant experts."

DEA Response: DEA regulations provide that "[a]ny interested person" may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811]." 21 CFR 1300.01(b). The regulations further require that any person requesting a hearing must state "with particularity" his interest in the proceeding. 21 CFR 1316.47(a). Because the commenter failed to provide sufficient information to demonstrate that he meets the definition of "interested person" as set forth in the regulations, DEA hereby denies this hearing request.

Other Comments

The remaining comments were concerning various topics, not all of them being related to lorcaserin directly. The comments are summarized below as follows:

- Several commenters were critical of DEA's handling of the scheduling process. The commenters did not provide specific recommendations for action.
- One commenter expressed concern about the abuse potential of lorcaserin. The commenter did not indicate whether they opposed or supported the proposal to control lorcaserin.
- One commenter requested that DEA extend the comment period for the NPRM by 60 additional days. The commenter indicated that the public had not been given sufficient time to respond to the NPRM. DEA has allowed 30 days for a comment period in previous scheduling actions for new chemical entities. A 30-day comment period has been demonstrated to be a sufficient period to allow the public to submit comments to proposed scheduling actions.
- One commenter submitted information about Combo Pilling, which is not related to the current control action.
- One commenter discussed the side effects experienced with taking Qsymia, a weight loss drug. This comment was not related to the current scheduling action.
- Two commenters stated that obesity drugs are not needed to deal with the current obesity epidemic. This comment was not related to the current scheduling action.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of lorcaserin. As such, DEA will schedule lorcaserin as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as Schedules I, II, III, IV, and V. The statute outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) Lorcaserin has a low potential for abuse relative to the drugs or other substances in Schedule III. The overall abuse potential of lorcaserin is comparable to Schedule IV substances such as zolpidem;

(2) Lorcaserin has a currently accepted medical use in treatment in the United States. Lorcaserin HCL was approved for marketing by FDA as an addition to a reduced-calorie diet and exercise, for chronic weight management; and

(3) Abuse of lorcaserin may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. This finding is based on the ability of lorcaserin to produce positive subjective effects at supratherapeutic doses.

Based on these findings, the Administrator of DEA concludes that lorcaserin, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants

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control in Schedule IV of the CSA (21 U.S.C. 812(b)(4)).

Requirements for Handling Lorcaserin

Upon the effective date of this final rule, lorcaserin is subject to the CSA and the Controlled Substances Import and Export Act (CSIEA) regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a Schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with lorcaserin, or who desires to manufacture, distribute, dispense, import, export, engage in research or conduct instructional activities with lorcaserin, must be registered to conduct such activities pursuant to 21 U.S.C. 822 and in accordance with 21 CFR Part 1301. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 7, 2013 and may not continue their activities until DEA has approved that application.

Security. Lorcaserin is subject to Schedules III–V security requirements and must be manufactured, distributed, and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 on or after June 7, 2013.

Labeling and Packaging. All labels and labeling for commercial containers of lorcaserin must be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825, on or after June 7, 2013.

Inventory. Every registrant required to keep records and who possesses any quantity of lorcaserin must keep an inventory of all stocks of lorcaserin on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.06, and 1304.11 on or after June 7, 2013. Every registrant who desires registration in Schedule IV for lorcaserin is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 on or after June 7, 2013.

Prescriptions. All prescriptions for lorcaserin or prescriptions for products containing lorcaserin must comply with 21 U.S.C. 829 and 21 CFR 1306, including but not limited to 21 CFR 1306.03–1306.06, 1306.08, 1306.09, and 1306.21–1306.27 on or after June 7, 2013.

Importation and Exportation. All importation and exportation of lorcaserin must be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958, on or after June 7, 2013.

Criminal Liability. Any activity with lorcaserin not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after June 7, 2013.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place lorcaserin, including its salts, isomers and salts of isomers, into Schedule IV of the CSA. By this final rule, lorcaserin will remain in Schedule IV unless and until additional scheduling action is taken to either transfer it between the schedules or to remove it from the list of schedules. See 21 U.S.C. 811 and 812. No less restrictive measures (i.e., non-control) enable DEA to meet its statutory obligations under the CSA.

Lorcaserin is a new chemical entity and is not currently available or marketed in any country. According to publicly available information reviewed by DEA, lorcaserin is anticipated to enjoy patent protection for at least a decade before generic equivalents may be manufactured and marketed. Accordingly, the number of currently identifiable manufacturers, importers, and distributors for lorcaserin is extremely small. The publicly available materials also specify the readily identifiable persons subject to direct regulation by this final rule. Based on guidelines utilized by the Small Business Administration, the lorcaserin manufacturer was identified as a small entity and is expected to conduct manufacturing activities at a facility outside the United States; the distributor/importer does not meet the standard as a small entity. Once generic equivalents are developed and approved for manufacturing and marketing, there may be additional manufacturers, importers, and distributors of lorcaserin, but whether they may qualify as small entity cannot be determined at this time.

There are approximately 1.4 million controlled substance registrants, approximately 381,000 of which are estimated to be businesses. DEA estimates that 371,000 (97%) of these businesses are considered "small entities" in accordance with the RFA and Small Business Administration standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. However, due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the dispensing rates of new chemical entities, DEA is unable to determine the number of small entities which might dispense (including administer or prescribe) lorcaserin (e.g., pharmacies and prescribers).

Despite the fact that the number of small businesses possibly impacted by this rule could not be determined, DEA concludes that they would not experience a significant economic impact as a result of this rule. Currently

98% of DEA registrants (most of which are small businesses) are authorized to handle Schedule IV controlled substances. Even if we assume that all of these registrants were to handle lorcaserin (e.g., practitioners prescribe the substance, and pharmacies dispense those prescriptions), the costs that they would incur as a result of lorcaserin's scheduling would be nominal. Registrants that dispense (but not prescribe) would incur nominal additional security, inventory, recordkeeping, and labeling costs. These registered entities have already established and implemented these systems and processes required to handle Schedule IV controlled substances, and can easily absorb the costs of dispensing lorcaserin with nominal to no additional economic burden. For example, pharmacies and institutional practitioners may disperse Schedule II through V controlled substances throughout the stock of noncontrolled substances in such a manner as to obstruct theft or diversion of the controlled substances. In addition, because registered pharmacies must label all Schedule II through V controlled substances that they dispense, the requirement to label all dispensed substances containing lorcaserin would not impose a significant economic burden upon registered pharmacies. Accordingly, compliance would not require significant additional manpower, capital investment, or recordkeeping burdens.

The only additional requirement imposed by this rule upon registrants that only prescribe substances containing lorcaserin is that they issue an oral or written prescription to dispense the substance. Accordingly, registered prescribers would not incur any additional security, inventory, recordkeeping, or labeling costs as a result of this rule as they would not physically handle lorcaserin.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

For the reasons stated in the above section titled, "Regulatory Flexibility Act,"[3] this rule does not include a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995 (UMRA).

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this Final Rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100) the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 1. Section 1308.14 is amended by redesignating paragraphs (e) and (f) as paragraphs (f) and (g), and adding a new paragraph (e) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(e) *Lorcaserin.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Lorcaserin 1625

* * * * *

Dated: April 29, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–10895 Filed 5–7–13; 8:45 am]

BILLING CODE 4410–09–P

[3] UMRA and the RFA share the same definition of "rule." UMRA defines "regulation" or "rule" by cross-referencing the RFA's definition of "rule." 2 U.S.C. 658(10)). The RFA generally defines "rule" as "any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of [the Administrative Procedure Act]." 5 U.S.C. 601(2).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 09–197; 11–42; FCC 13–44]

Telecommunications Carriers Eligible for Support; Lifeline and Link Up Reform and Several Petitions for Forbearance

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this order, the Federal Communications Commission (Commission) grants limited forbearance from the requirement of the Commission's rules that the service area of an eligible telecommunications carrier (ETC) conform to the service area of any rural telephone company serving the same area. In particular, this grant of forbearance applies to any ETC that has been designated by a state or the Commission, as well as pending and future requests by telecommunications carriers that seek limited designation, as an ETC to participate only in the Lifeline program (Lifeline-only ETC). The Commission concludes that forbearance furthers the Act's and Commission's goals of ensuring the availability of voice service to low-income consumers.

DATES: Effective June 7, 2013, except paragraph 19 which is effective upon release of the Memorandum Opinion and Order.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–0428 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Memorandum Opinion and Order (Order) in WC Docket Nos. 09–197;11–42; FCC 13–44, released on April 15, 2013. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. Or at the following Internet address:

Virginia Board of Pharmacy
2014 Session of the General Assembly

DRAFT LEGISLATION

A BILL to amend and reenact § 54.1-3452 of the Code of Virginia, relating to addition of the drug lorcaserin to the list of Schedule IV controlled substances.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazapam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine~~;~~

Lorcaserin.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical,

position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter

if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section

TRAMADOL
(Trade Names: Ultram®, Ultracet®)

March 2013
DEA/OD/ODE

Introduction:

Tramadol was approved for marketing as a noncontrolled analgesic in 1995 under the trade name of Ultram®. Although the company initially claimed that this substance produced only very weak narcotic effects, recent data demonstrate that opioid activity is the overriding contributor to the drug's pharmacological activity. Because of inadequate product labeling and lack of established abuse potential, many physicians felt this drug was safe to prescribe to recovering narcotic addicts and to known narcotic abusers. As a consequence, numerous reports of abuse and dependence have been received.

Licit Uses:

Tramadol is approved for the treatment of moderate to moderately severe pain in adults. According to the IMS Health National Prescription Audit Plus™, retailers dispensed 39.8 million tramadol prescriptions in 2012.

Chemistry/Pharmacology:

Tramadol is a novel analgesic having both opiate agonist activity and monoamine reuptake inhibition that contribute to its analgesic efficacy. Opioid activity is due to both the parent compound and the more active O-desmethylated metabolite. Tramadol acts on the monoamine reuptake systems by inhibiting the reuptake into nerve terminals of both norepinephrine and serotonin.

Apart from analgesia, tramadol may produce a number of symptoms including dizziness, somnolence, nausea, and constipation similar to other opioids. High doses of tramadol, often in combination monoamine oxidase (MAO) inhibitors or serotonin-selective reuptake inhibitors (SSRIs), have been associated with a serotonin syndrome consisting of convulsions, hyperthermia, muscle rigidity and pain.

Tramadol is well absorbed orally. It can be administered in 50 to 100 mg tablets as needed for pain relief every 4 to 6 hours, not to exceed 400 mg/day. Seizures have occurred in patients taking recommended doses but are more likely at high doses associated with abuse of this medication. Tolerance, dependence and addiction to tramadol have been demonstrated. Abrupt cessation from tramadol has been associated with two types of withdrawal syndromes. One is typical of opioid drugs with flu-like symptoms, restlessness and drug craving. This type of withdrawal syndrome is encountered in about 90 percent of cases of withdrawal from tramadol. Another withdrawal syndrome (encountered in about 10 percent of cases of tramadol withdrawal) is atypical of opioids and is associated with hallucinations, paranoia, extreme anxiety, panic attacks, confusion, and numbness and tingling in the extremities.

The FDA-approved labeling for tramadol has been modified several times to include new information under the "Drug Abuse and Dependence" section. This section of the labeling currently contains the following language:

> Tramadol hydrochloride may induce psychic and physical dependence of the morphine-type (μ-opioid). Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients with prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. Tramadol hydrochloride is associated with craving and tolerance development. Withdrawal symptoms may occur if tramadol hydrochloride is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection and rarely hallucinations. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by gradual, tapered dose reduction of the medication combined with symptomatic support.

Abuse and Diversion:

Tramadol is most commonly abused by narcotic addicts, chronic pain patients, and health professionals.

According the American Association of Poison Control Centers, there were a total of 12,424 tramadol exposures in 2011. Of this total in 2011, there were 6,361 single substance exposures (6 deaths) associated with tramadol.

The Drug Abuse Warning Network (DAWN) reported that in 2010. 16,251 emergency department visits were related to tramadol nonmedical use.

According to the National Survey on Drug Use and Health (NSDUH), 2.6 million people in the U.S. aged 12 or older used tramadol for nonmedical purposes in 2011.

The National Forensic Laboratory Information System (NFLIS) is a DEA database that collects scientifically verified data on drug items and cases submitted to and analyzed by state and local forensic laboratories. The System to Retrieve Information from Drug Evidence (STRIDE) provides information on drug seizures reported to and analyzed by DEA laboratories. Of the exhibits submitted to federal, state and local forensic laboratories in 2011, 1,692 were identified as tramadol. To date, 1,708 of the exhibits submitted to forensic laboratories in 2012 are identified as tramadol.

Controlled Status:

Tramadol is not currently controlled under the CSA. Arkansas, Illinois, Kentucky, Mississippi, New Mexico, New York, North Dakota, Ohio, Oklahoma, Tennessee, West Virginia and Wyoming have designated tramadol as a schedule IV drug under state law. Louisiana passed legislation that identifies tramadol as a drug of abuse; demonstrating potential for abuse.

Comments and additional information are welcomed by the Office of Diversion Control, Drug and Chemical Evaluation Section. Fax 202-353-1263, Telephone 202-307-7183, or Email ODE@usdoj.gov.

Virginia Board of Pharmacy
201[illegible] Session of the General Assembly

DRAFT LEGISLATION

A BILL to amend and reenact § 54.1-3452 of the Code of Virginia, relating to addition of the drug tramadol to the list of Schedule IV controlled substances.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazapam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine.;

Tramadol.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not

having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Virginia Board of Pharmacy
2014 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-3304.1 of the Code of Virginia authorizing issuance of permits for facilities where practitioners of the healing arts dispense controlled substances.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3304.1. Authority to license and regulate practitioners; permit to sell controlled substances.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any person to dispense controlled substances within this Commonwealth unless licensed by the Board as a practitioner of the healing arts to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances.

Virginia Board of Pharmacy
2014 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-2408.1 of the Code of Virginia relating to summary suspension authority of any health regulatory board.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2408.1 of the Code of Virginia is amended and reenacted as follows:

54.1-2408.1. Summary action against licenses, certificates, registrations, or multistate licensure privilege or permit; allegations to be in writing.

A. Any health regulatory board may suspend the license, certificate, registration, permit, or multistate licensure privilege of any person holding a license, certificate, registration, permit, or licensure privilege issued by it without a hearing simultaneously with the institution of proceedings for a hearing, if the relevant board finds that there is a substantial danger to the public health or safety which warrants this action. A board may meet by telephone conference call when summarily suspending a license, certificate, registration, permit, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension.

B. Any health regulatory board may restrict the license, certificate, registration, permit, or multistate licensure privilege of any person holding a license, certificate, registration, permit, or licensure privilege issued by it without proceeding simultaneously with notification of an informal conference pursuant to §§ 2.2-4019 and 54.1-2400, if the relevant board finds that there is a substantial danger to the public health or safety that warrants this action. A board may meet by telephone conference call when summarily restricting a license, certificate, registration, permit, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. The informal conference shall be scheduled within a reasonable time of the date of the summary restriction.

C. Any health regulatory board may require holders of licenses, certificates, registrations, multistate licensure privilege or permit that have been summarily suspended or restricted pursuant to this section to take additional actions as may be required by such health regulatory board to avoid further substantial danger to the public health or safety.

~~C.~~D. Allegations of violations of this title shall be made in writing to the relevant health regulatory board.

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

A wholesale distributor that ceases distribution of controlled substances in Schedules II-V to a licensed dispenser for reasons other than nonpayment shall notify the Board of Pharmacy within 5 days of this decision.

Board of Pharmacy
Chart of Regulatory Actions as of June 1, 2013

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Administrative fees for duplicate licenses and verification Stage: Proposed - *At Secretary's Office for 666 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:  Less restrictive and burdensome record-keeping for on-hold prescriptions Stage: Proposed - *Register Date: 6/3/13* *Comment period: 6/3/13 to 8/2/13*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:  Modifications to requirements for automated dispensing devices for less burdensome process Stage: Proposed - *Register Date: 6/3/13* *Comment period: 6/3/13 to 8/2/13*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Continuous quality improvement programs Stage: Proposed - *At Governor's Office for 45 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Addressing hours of continuous work by pharmacists Stage: Proposed - *At Secretary's Office for 22 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:  Change to run-dry requirement for automated counting devices Stage: Fast-Track - *Register Date: 6/17/13* *Effective: 8/2/13*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:  Regulatory reform changes Stage: Fast-Track - *DPB Review in progress*
Regulations for Practitioners of the Healing Arts to Sell Controlled Substances [18 VAC 110 - 30]	Action:  Regulatory reform Stage: Fast-Track - *Register Date: 6/17/13* *Effective: 8/2/13*
Regulations Governing Wholesale Distributors, Manufacturers and Warehousers [18 VAC 110 - 50]	Action:  Regulatory reform Stage: Fast-Track - *Register Date: 6/17/13* *Effective: 8/2/13*

NABP Verified Pharmacy Program™

Providing a vital resource for the boards of pharmacy for use in making licensure and registration determinations.

In the wake of the New England Compounding Center (NECC) tragedy, member state boards of pharmacy have spoken out very clearly about the need to build uniformity among the states and through enhanced services from National Association of Boards of Pharmacy® (NABP®). Due to the strength and leadership of its member boards, NABP has a strong foundation to rapidly assist as well as build and deploy services to assist member boards in their charge to protect the public health.

What?

Developing a Unified Resource

NABP is in the process of developing the Verified Pharmacy Program™ (VPP™), through which the Association will create pharmacy e-Profiles to unify imperative licensee data and inspection report components for the boards. Housed in the Board e-Profile Connect interface, these e-Profiles will be pre-populated and proactively reported to member boards with all information needed to make effective licensing decisions. This information will include:

1. Verification of pharmacy licenses (resident and nonresident).
2. Verification of pharmacist-in-charge licenses (resident and nonresident).
3. Disciplinary information.
4. Verification that a qualified inspection has been performed by the resident state or a designated agent.

Why?

Current Nonresident Pharmacy Regulatory Structure

State boards of pharmacy must be able to make informed decisions about the facilities they regulate. At times, boards are asked to make licensing decisions about nonresident pharmacies with incomplete or outdated information from the facility's resident board of pharmacy. Differing levels of resources among boards of pharmacy create significant gaps in the frequency and type of inspections states can conduct, as well as the level of due diligence states can perform on their regulated entities.

How?

Existing NABP Infrastructure

NABP provides a wide range of services to assist member boards. These include, but are not limited to, license verification; Electronic Licensure Transfer Program® (e-LTP™); NABP Clearinghouse, which includes disciplinary information; accreditation; and inspection services. These already existing services are the foundation for NABP to assist member boards in addressing the gaps in the nonresident pharmacy regulatory structure.

Continued on back.

Enhancement of Existing Services

NABP was founded around a need to facilitate license transfer for pharmacists across state lines. The NECC tragedy has caused all boards to revisit their licensing and information sharing processes for nonresident pharmacies and explore new ways to better regulate these out-of-state actors. Many boards have approached NABP about providing inspection services, creating an information sharing network for nonresident pharmacies, and even creating a license transfer program for nonresident facilities.

Through enhancement of existing programs and services to member boards, NABP will:

1. Extrapolate the success of e-LTP and apply it to pharmacies and facilities, beginning first with nonresident pharmacies.
2. Create an interconnected e-Profile for each pharmacist, pharmacy technician, and pharmacy.
3. Verify that a qualified inspection has been conducted by a resident board of pharmacy or NABP.

Assistance from Member Boards

NABP cannot do this alone. In order to establish VPP, the uniform license transfer program for pharmacies, the Association must have the leadership and guidance of its member boards.

Together, we will need to:

1. Establish and identify uniform inspection standards across multiple practice settings, ranging from routine inspection to inspections following United States Pharmacopeial Chapters 795 and 797 guidelines.
2. Establish these uniform inspection standards in a manner similar to NABP's competency assessment and accreditation programs.
3. Share examination scores, license status changes, and disciplinary actions in real time between and among NABP and its member boards, which will save board staff time and increase automation and efficiency.

National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056
(P) 847/391-4406 • (F) 847/391-4502 • *www.nabp.net*

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit ~~Most Recent~~ Current Inspection ~~Form~~ Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

...

As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of ~~the most recent~~ a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted ~~within the past five years~~ (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the ~~past five years~~ required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) ~~following entities~~ that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.~~:~~

~~The National Association of Boards of Pharmacy (NABP)~~
~~Joint Commission for the Accreditation of Health Care Organizations (JCAHO)~~

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with

applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <51> Antimicrobial Effectiveness Testing, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

   When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***
   No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

5. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

   Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

6. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

   EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

7. ***Do batches less than 25 require sterility testing to be performed?***

   No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> when:
   - high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
   - in multiple-dose vials (MDVs) for administration to multiple patients or
   - CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized before they are dispensed or administered.

8. ***How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?***

   Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.

***Note- this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

9. ***Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?***

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

10. ***How often must media-fill testing be performed?***

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note - the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively.

11. ***If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?***

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note- this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. ***Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?***

Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

13. ***Does USP-NF address how long a CSP may hang for infusion?***

No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

14. ***May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?***

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

15. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.
- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

17. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed.

Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

18. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

19. *How should a dilution or stock bag for pediatrics be treated?*

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of administration.

20. What concepts, at a minimum, should be taken into consideration when determining drug stability?

Pharmacists should use professional judgment to determine appropriate references of chemical stability information. When relying on information in studies, pharmacists should have at least two articles which justify the assigned stability. If stability is determined by extrapolating information from a reference source, then the pharmacist must ensure that the drug stability in the reference source is not concentration dependent. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

21. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.

22. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual

testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

23. How often must air and surface sampling be performed?

USP requires air and surface sampling to be performed "periodically". The Board advises that air and surface sampling should be performed at least annually. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). It may be performed by pharmacy personnel or outsourced.

24. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certifying companies must comply with guidelines published by the Controlled Environment Testing Association (CETA). Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with CETA guidelines. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

25. What minimally should be taken into consideration when compounding multidose vials?

Multidose vials of CSPs must comply with USP Chapter <51>. It must be determined that the preservative being used is bacteriostatic, fungistatic, effective at maintaining sterility for 28 days, and does not interact with the drug. Antimicrobial preservatives cannot be used as a substitute for good compounding practices.

26. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

27. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

28. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- Not more than 3520 particles (0.5 μm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-μm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

29. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

30. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

31. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

32. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes. USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

33. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

34. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at

https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

Board of Pharmacy Sanctioning Reference Points Instruction for Pharmacists

Case Type

Step 1: (score only one)
Enter the point value that corresponds to the case type. If a case has multiple aspects, enter the point value for the one most serious case type that is highest on the list.

A. Enter "70" if case involves an Inability to Safely Practice. These cases include:
- Inability to Safely Practice: Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions
- Drug Related – Patient Care: Dispensing in violation of DCA (to include dispensing for non-medicinal purposes, excessive prescribing, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use

B. Enter "25" if the case involves Professional Practice Issues. These cases include:
- Business Practice Issues: records, audits, required report not filed, or disclosure
- Drug Related – Security: Failure to maintain security of controlled substances
- Fraud – Patient Care: falsification/alteration of patient records
- Confidentiality Breach: disclosing unauthorized client information without permission or necessity

C. Enter "10" if the case involves a Prescription Error. These cases include:
- Standard of Care – Medication/Prescription: labeling, dispensing, and administration errors, failure to provide counseling as well as other medication/prescription related issues
- Standard of Care – Other

Offense and Respondent

Step 2: (score all that apply)

A. Enter "60" if there was financial or other material gain from the offense.
B. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
C. Enter "50" if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/ or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bono fide health care practitioner.
D. Enter "35" if there are two or more concurrent founded violations during the same proceeding. This includes two or more cases against a respondent heard at the same time, with violations for each case.
E. Enter "35" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.
F. Enter "15" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.
G. Enter "5" if the respondent has had one or more prior Board violations.

Step 3: Combine all for Total Worksheet Score. Locate the Total Worksheet Score with the Sanction Threshold Levels table at the bottom of the worksheet. The scores correspond to one of the three SRP recommendations.

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Monetary Penalty" area with a score of 40, the Board may choose a sanction package that includes a "Monetary Penalty" and a "Reprimand" and still be in agreement with the SRP recommendation.

Board of Pharmacy - Sanctioning Reference Points Worksheet for Pharmacists

Case Type (score only one)	Points	Score
A. Inability to Safely Practice	70	
B. Professional Practice Issues	25	
C. Prescription Error	10	

Offense and Repsondent (score all that apply)		
A. Financial/Material gain	60	
B. Respondent impaired during incident	50	
C. Any past substance abuse or treatmer	50	
D. Multiple violations associated with cas	35	
E. Act of commission	35	
F. Patient injury	15	
G. Any prior violations	5	

Total Worksheet Score ☐

Score	Sanctioning Recommendations	Fine Amounts
0-35	No Sanction/Reprimand/CE	N/A
36-115	Monetary Penalty	$250 to $1500
116 and up	Treatment/Monitoring/Recommend Formal	$1000 and up

Respondent Name: _____ Date: _____

Confidential pursuant to § 54.1-2400.2 of the Code of Virginia