COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor (804) 367-4456 (Tel)
Henrico, Virginia 23233 (804) 527-4472(Fax)

Tentative Agenda of Public Hearing and Full Board Meeting

December 12, 2013

9:00AM

TOPIC	PAGE(S)

Call to Order of Public Hearing on Regulations 18VAC110-20-10 et seq.:
Jody H. Allen, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Continuous Quality Improvement Programs — A-K

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Jody H. Allen, Chairman

- Approval of Agenda
- Approval of previous Board meeting minutes:
  - September 9, 2013, Regulation Committee regarding Emergency Medical Services Agencies — 1-9
  - September 10, 2013, Full Board Meeting — 10-21
  - October 7, 2013, Informal Conference Committee — 22-27
  - October 15, 2013, Summary Suspensions — 28-30
  - October 15, 2013, Panel Formal Hearing — 31-34
  - October 17, 2013, Special Conference Committee & Informal Conference Committee — 35-37
  - November 7, 2013, Telephone Conference Call — 38-39
  - November 12, 2013, Special Conference Committee & Informal Conference Committee — 40-43
  - November 25, 2013, Regulation Committee — Handout
  - November 25, 2013, Ad Hoc on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense — Handout

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.

Regulatory Actions: Elaine Yeatts

- Regulatory Update 44
- Adoption of Comment to DEA on Proposal to Place Tramadol into Schedule IV 45-53
- Report from the Regulation Committee for Drug Diversion and Responsibility of Pharmacist-in-Charge to Provide Adequate Safeguards 54-58

Miscellaneous: Caroline D. Juran

- Report from the Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense 59-71

Old Business:

- Request from VPhA to Reconvene Ad Hoc Committee on Sterile Compounding 72-82

Reports:

- Chairman's Report – Jody H. Allen
- Report on Board of Health Professions – Robert M. Rhodes
- Report on NABP District 1 and 2 Meeting – Cynthia Warriner 83-86
- Report on Licensure Program – J. Samuel Johnson, Jr. Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report - Caroline D. Juran 87-93

New Business:

Presentation of Consent Orders (if any)

Presentation of Possible Summary Suspensions

Adjourn

***The Board will have a working lunch at approximately 12pm. Immediately following adjournment of the meeting, a panel of the Board will be convened for formal hearings.**

Proposed Regulations – Comment Period from November 18, 2013 to January 17, 2014

BOARD OF PHARMACY

Continuous quality improvement programs

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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"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.

A

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"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.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

C

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"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.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"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.

E

"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.

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

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B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 Code of Virginia and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

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DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE REGARDING EMERGENCY MEDICAL SERVICES AGENCIES

September 9, 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 2:10PM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT: R. Crady Adams
Empsy Munden
Dinny Li
Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented. (motion by Adams, second by Munden)

LICENSED EMERGENCY MEDICAL SERVICE AGENCIES PROGRAM: Amendments to 18VAC110-20-500 were adopted as an exempt regulatory action at the full board meeting on June 18, 2013. The Regulation Committee met to review Regulation 18VAC110-20-500 and determine if additional amendments are needed. The Committees' recommendation resulting from this meeting will be reported to and considered by the full Board at the September 10, 2013 full board meeting.

Verbal comment was received and heard for approximately two hours by the committee. Michael D. Berg, Manager, Regulation and Compliance with the Virginia Department of Health Office of Emergency Medical Services provided information and answered questions from committee members. Comments offered by staff considered during the discussion included: sealing and securing the drug kit, inventory and reporting loss of drugs, verification of drug box contents, records, destruction of drugs, exchange of drug by the emergency department, and one-for-one drug exchange. Elaine Yeatts advised the Committee that the amendments can be adopted by the Board as fast-track regulatory action.

MOTION: **The Committee voted unanimously to recommend to the full board for its consideration the proposed amendments to Regulation 18VAC110-20-500 as indicated in Attachment 1. (motion by Munden,** second by **Adams)**

ADJOURN: With all business concluded, the meeting adjourned at 4:14PM.

Cynthia Warriner, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

Attachment 1

Recommendation from the Regulation Committee

September 9, 2013

18VAC110-20-10. Definitions.

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"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.

"EMS" means emergency medical services.

"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 which have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

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"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.

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"Quality assurance plan" means a plan approved by the board for on-going 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" is 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.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a drug kit for a licensed ~~emergency medical services~~ EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The drug kit is sealed, secured and stored in such a manner that it will deter theft or loss of drugs and aid in detection of such.

a. The hospital pharmacy shall have a method of sealing the drug kits such that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs may be administered by an ~~emergency medical technician~~ EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with §54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the ~~technician~~ EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the emergency medical services agency. A current copy of the signed standing protocols shall be maintained by the pharmacy participating in the kit exchange. The ~~emergency medical technician~~ EMS provider shall make a record of all drugs administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. A pharmacist, pharmacy technician, or nurse shall perform an inventory of Schedule II, III, IV or V drugs in the kit at the time the opened kit is returned. A record of the inventory, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. ~~An accurate record~~ Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year~~:~~:

a. The record of filling and verifying the kit to include the drug contents of kit, the initials of the pharmacist verifying the contents, date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit which shall be no later than the expiration date associated with the first drug scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, or prescriber. Documentation shall be maintained for a period of two years from the date of destruction.

7. The record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the drug kit.

9. Any controlled substance showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse or prescriber.

B. In lieu of obtaining replacement intravenous fluids, irrigation fluids, heparin flush kits, sterile water and saline, and prescription devices via the exchanging of the drug kit, a licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of such drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02, the EMS provider may directly obtain intravenous fluids, irrigation fluids, heparin flush kits, sterile water and saline, and prescription devices from an automated drug dispensing device. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 10, 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 9:10 am.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Ellen B. Shinaberry, Vice-Chairman
Crady R. Adams
David Kozera
Dinny Li
Empsy Munden
Robert M. Rhodes
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
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Erin Barrett, Assistant Attorney General- arrived 3:00 p.m.

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

APPROVAL OF AGENDA: Staff presented an addition to the agenda which was a handout of the draft set of minutes from the September 4, 2013 Special Conference Committee. The agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the June 18, 2013 (Public Hearing), June 18, 2013 (Full Board Meeting), June 18, 2013 (Panel Formal Hearing), June 21, 2013 (Informal Conference Committee), July 17, 2013 (Telephone Conference Call), July 24, 2013 (Informal Conference Committee), July 25, 2013 (Panel Formal Hearing), July 25, 2013 (Informal Conference Committee and Special Conference Committee), August 20, 2013 (Ad Hoc on Collaborative Practice Agreements), August 20, 2013 (Special Conference Committee and Informal Conference Committee), August 21, 2013 (Telephone Conference Call), and September 4, 2013 (Special Conference Committee).

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

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PUBLIC COMMENTS:

The Board received comments from two individuals. Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA), stated that the VPhA had questions regarding Guidance Document 110-36. He requested that the Board reconvene the ad hoc committee for further consideration of the guidance. He then introduced Loyd V. Allen, Jr., Ph.D, R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and *Remington: The Science and Practice of Pharmacy*. Dr. Allen briefly described his experience working as a volunteer member with the U.S. Pharmacopeial (USP) Convention and with the subject of sterile compounding. He prefaced that his comments were his own and not representative of the USP. He provided a handout (Attachment 1) which summarized his concerns with three of the numbered items within Guidance Document 110-36. He stated that USP chapters, such as Chapter <71>, were originally written for manufacturing with later standards written for pharmacy compounding. He is in the process of discerning which chapters he believes apply to manufacturing verses pharmacy compounding; he believes the numbered items referenced in his handout need further clarification. Ms. Allen thanked Mr. Musselman and Dr. Allen for their comments.

DHP DIRECTOR'S REPORT:

Dianne Reynolds-Cane, M.D., Director of the Department of Health Professions (DHP), was unable to attend the meeting due to a scheduling conflict. Arne Owens, Chief Deputy Director, DHP, presented the Director's report on her behalf. Mr. Owens reported that the state plan to reduce prescription drug abuse was submitted to the National Governors Association (NGA) on August 30, 2013. The plan consists of various suggestions and ideas to assist in the reduction of prescription drug abuse. Mr. Owens stated that DHP hosted the NGA Prescription Drug Abuse Policy Reduction meeting on March 25, 2013, and was one of the several state agencies that participated.

A request was made by staff to modify the agenda to include the Regulation Committee recommendation from the meeting that was held on September 9, 2013, regarding 18VAC 110-20-500 concerning emergency medical services (EMS) agencies.

MOTION:

The Board voted unanimously to modify the agenda to include the Regulation Committee recommendation regarding 18VAC 110-20-500 concerning emergency medical services agencies. (motion by Warriner, second by Thornbury)

REGULATIONS:

Ms. Yeatts highlighted certain regulatory activities as included on the update on page 37 of the agenda packet. The request for an extension of the emergency regulations for continuous quality improvement programs (CQI) is currently at the Governor's office. If approved, this will extend the emergency regulations until April 1, 2014. The change to run-dry requirements for automated counting devices was fast-tracked and has been in effect since August 2, 2013. The regulatory reform changes were also fast-tracked, and will become effective on September 26, 2013. The exempt regulatory action for the administration of drugs by emergency

medical services personnel become effective September 25, 2013.

FINAL ADOPTION OF PROPOSED AMENDMENTS FOR AUTOMATED DISPENSING DEVICES AND ON-HOLD PRESCRIPTIONS:

Ms. Yeatts reviewed the proposed amendments along with public comment received regarding the regulations for automated dispensing devices. A comment received from John Lubkowski suggested an amendment to section C2 of 18 VAC 110-20-490 to allow a discrepancy to be reported to the pharmacist-in-charge or his designee. Ms. Yeatts stated that the Board could consider making additional changes to the regulations per the public comment or adopt as presented. Several board members explained the importance of ensuring that the PIC is immediately informed of a discrepancy and did not believe it was appropriate to delegate another individual to receive this information.

MOTION:

The Board voted unanimously to not include the suggested language to allow a discrepancy to be reported to the designee of the pharmacist-in-charge and to leave the language as written. (motion by Adams, second by Rhodes)

MOTION:

The Board voted unanimously to adopt the final regulation 18 VAC 110-20-490 for automated dispensing devices as presented. (motion by Warriner, second by Kozera)

Ms. Yeatts reviewed the proposed amendments along with public comment received regarding the regulations for on-hold prescriptions.

MOTION:

The Board voted unanimously to adopt the final regulations for on-hold prescriptions as presented. (motion Rhodes, second by Kozera)

ADOPTION OF PROPOSED AMENDMENTS TO REGULATIONS GOVERNING COLLABORATIVE PRACTICE AGREEMENTS:

An ad hoc committee of the Boards of Pharmacy and Medicine met on August 20, 2013, to discuss possible amendments to the regulations governing collaborative practice agreements as a result of statutory changes from the passing of HB 1501. Ms. Yeatts explained that the committee recommended the adoption of the proposed amendments with the exception of 18 VAC 110-40-40 if counsel later indicated that the added language would not qualify as an exempt action. Ms. Yeatts reported that counsel did not believe the proposed added language in 18 VAC 110-40-40 conformed with exempt regulatory action requirements. The Board concluded that the suggested language in 18 VAC 110-40-40 was not necessary.

MOTION:

The Board voted unanimously to adopt the proposed exempt regulatory amendments to 18 VAC 110-40-10 and 18 VAC 110-40-20 regarding collaborative practice agreements as recommended by the ad hoc committee. (motion by Warriner, second by Shinaberry)

ADOPTION OF PROPOSED AMENDMENTS TO REGULATIONS FOR EMERGENCY MEDICAL SERVICES AGENCIES (EMS)

The Regulation Committee met on September 9, 2013, to discuss possible amendments to regulation 18 VAC 110-20-500 concerning the licensed emergency medical services (EMS) agencies program. It was the recommendation of the committee that the Board adopt the amended regulations as a fast-track regulatory action. It was recommended that the

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PROGRAMS:

committee's proposed language in new section A 4 of 18 VAC 110-20-500 be changed from "perform an inventory of" to "reconcile the" and change the subsequent term "inventory" to "reconciliation".

MOTION:

The Board voted unanimously to adopt the proposed fast-track regulatory amendments of 18 VAC 110-20-500 regarding emergency medical services (EMS) agencies programs as recommended by the Regulation Committee and amended by the Board. (motion by Munden, second by Warriner)

SANCTIONING REFERENCE POINTS RESULTS FOR PHARMACY TECHNICIANS:

Neal Kauder and Kim Small with Visual Research, Inc., reviewed the sanctioning reference points (SRP) results for pharmacy technicians and presented a proposed worksheet to assist the Board during informal conference deliberations of pharmacy technicians. The worksheet is intended to be used in an analogous manner as the worksheet for pharmacists that the Board has used for several years. The goal for its use is to aid the board in determining appropriate disciplinary action in a consistent manner. Mr. Kauder stated that their review indicated there is not as much variability in case decisions for pharmacy technicians. The Board discussed the worksheet and made several changes by correcting a typo and removing language which did not pertain to pharmacy technicians. Mr. Kauder indicated he will provide staff with the final version reflecting the Board's amendments which can be posted online.

MOTION:

The Board voted unanimously to accept the Sanctioning Reference Points Worksheet for Pharmacy Technicians as amended. (motion by Kozera, second by Adams)

ADOPTION OF AMENDED BYLAWS, GUIDANCE DOCUMENT 110-12:

The Board reviewed staff's suggestions for amending the bylaws in Guidance Document 110-12 as presented on page 68-71. Ms. Juran explained that the suggestions reflect the advice received in recent years from psychometricians responsible for assisting the Board in the development of the drug law examination and pharmacy technician examination, as well as agency policy for the issuance and consideration of a request for proposal (RFP). The Board made the following additional amendments: changed references to "Examination Committee" throughout the document to "Examination Administrator Selection Committee"; and, removed "and robotic pharmacy systems" in A 5 since the allowance to use robotic pharmacy systems is now in Board regulation and is no longer considered by the Pilot Committee.

MOTION:

The Board voted unanimously to adopt the amended bylaws in Guidance Document 110-12 as presented and amended. (motion by Warriner, second by Adams)

UPDATE ON 2012 PHARMACIST AND PHARMACY TECHNICIAN WORKFORCE SURVEYS:

Justin Crowe, Research Analyst for the Board of Health Professions, presented to the Board the 2012 results of the Workforce Survey for pharmacists and pharmacy technicians performed during the last renewal period in December 2012. Currently, twenty-three health professions are being surveyed by the Healthcare Workforce Data Center and a standard

template is being utilized that was established by a past committee. A goal is to streamline collected data so it is comparable across professions. Mr. Crowe reviewed the handouts with the Board and stated that comments may be received until September 25, 2013.

STAFF REQUEST TO CONVENE AD HOC INSPECTION COMMITTEE TO REVIEW GUIDANCE DOCUMENT 110-9 AND DEVELOP SIMILAR GUIDANCE FOR INSPECTIONS OF PHYSICIAN SELLING DRUGS:

Staff indicated that the routine pharmacy inspection process has been in use for three years and that it may be an appropriate time to thoroughly review Guidance Document 110-9 regarding suggested monetary penalties resulting from routine pharmacy inspections. Additionally, staff suggested that the Board consider developing similar guidance for inspections of physician selling drugs locations as a means of expediting the possible disciplinary action resulting from the increased number of physicians licensed to sell drugs.

MOTION:

The Board voted unanimously to convene the ad hoc committee to review Guidance Document 110-9 and consider the development of similar guidance for the routine inspections of physicians licensed to sell drugs. (motion Rhodes, second Kozera)

BOARD MEMBER REQUEST TO DISCUSS POSSIBLE DISCIPLINARY ACTION AGAINST PICS FOLLOWING DOCUMENTED LOSS OF CONTROLLED SUBSTANCES:

Mr. Adams distributed a handout (Attachment 2) that supported his concerns regarding the documented losses of controlled substances within a pharmacy and that the pharmacist-in-charge (PIC) should be held accountable for that loss. Mr. Adams stated that during his research, he discovered that in the first six months of the year 2013, only nine disciplinary actions, resulting from drug losses, were taken against a PIC. The document outlined sections of law and regulation identified by Mr. Adams which he stated supports the pharmacist's responsibility to appropriately secure controlled substances.

MOTION:

The pharmacist-in-charge (PIC) of a pharmacy that experiences either diversion or theft of Schedule II-VI drugs exceeding 100 oral tablets, or 100 usual oral liquid doses, or 25 ampules or vials shall be in violation of:

1. **18 VAC 110-20-25(6) Unprofessional Conduct: Failure to maintain adequate safe guards against diversion of controlled substances and,**
2. **Section 54.1-3434: Failure to provide safeguards against diversion of all controlled substances and,**
3. **18VAC 110-20-110(B) Pharmacy Permits: Failure to control all aspects of the practice of pharmacy and,**
4. **Section 54.1-3432: Failure to supervise the pharmacy and its personnel. The PIC shall be fined a minimum of $250 up to $5,000 and reprimanded. (motion by Adams, second by Stelly, 8 opposed, motion defeated)**

MOTION:

The Board voted unanimously to refer Mr. Adam's concerns for drug diversion and PIC accountability to the Regulation Committee for further research and to determine the best course of action. (motion by Stelly, second by Rhodes)

SCHEDULING OF DATES FOR THE 2014 FULL BOARD MEETINGS:

Ms. Juran presented available dates for the upcoming 2014 full board meetings. The Board unanimously agreed on the following dates: March 26, 2014; June 4, 2014; September 9, 2014; and December 9, 2014.

- Chairman's Report:

Ms. Allen reported that members to the standing committees for 2013-2014 have been appointed. Ms. Reiniers-Day will have the informal conference committee dates to those members within the next two weeks. Ms. Allen also reported that Ms. Warriner, Ms. Juran and herself have been appointed to taskforces of the National Association of Boards of Pharmacy (NABP) and will be participating in the near future.

- 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 last meeting was cancelled, but a review of older documents is planned for next year.

- Report on Licensure Program:

Mr. Johnson reported that the Board issued 1,425 licenses and registrations for the period of June 1, 2013 through August 31, 2013, including 454 pharmacists, 109 pharmacy interns, and 697 pharmacy technicians. Inspectors conducted 432 facility inspections including 233 routine inspections of pharmacies: 74 resulted in no deficiency, 57 with deficiencies, and 102 with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson reported that since April 1, 2013, pharmacy inspectors have identified that 95 (49%) of 193 pharmacies inspected were not compliant with the emergency regulations for continuous quality improvement programs. The most frequently occurring area of noncompliance was failure to indicate a zero report when no dispensing errors occurred within the past 30 days. Mr. Johnson reported that there are 138 open cases involving inspection deficiencies.

- 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 September 28, 2012; March 8, 2013; June 14, 2013; and September 9, 2013. For the final date, open cases are two at the entry stage; 59 at the investigation stage; 74 at the probable cause stage; 18 at the administrative proceedings division stage; 11 at the informal stage; six at the formal stage; and 145 at the pending closure stage.

- Executive Director's Report:

Ms. Juran reported that the e-newsletter was published at the beginning of August. It is available online and was sent via email to the pharmacists, pharmacy technicians, pharmacy interns, and pharmacies which have provided an email address to the Board. Ms. Juran also stated that she attended the Virginia Pharmacists Association (VPhA) meeting in Virginia Beach on July 30, 2013 and gave a law update on behalf of the Board. Mr. Johnson will be giving a law update at the upcoming Virginia Society of Health-System Pharmacists (VSHP) meeting in October. Ms. Juran requested travel authorization to attend the NABP/AACP District meeting in Maine which is being held October 17th through October 19th. A travel request was submitted and approved for the NABP Interactive Executive Officer Forum being held in Chicago, September 24th through

September 25th. Ms. Juran stated that NABP was covering all expenses and that she will be participating on a panel to discuss a blueprint to address compounding issues. Additionally, Ms. Juran received a $1,500.00 travel grant to attend the NASCSA meeting in Kansas City this October. Ralph Orr, Director of the Prescription Monitoring Program, will also be attending and is running for President. Ms. Juran is awaiting approval for this trip. The Virginia Prescription Monitoring Program (VPMP) is now interoperable with Tennessee which is Virginia's first border state to participate in the interoperability. A tentative stakeholder meeting has been set for either October 7th or 8th for the Department of Behavioral Health and Developmental Services naloxone project "REVIVE". NABP will subsidize the cost of the recently hired inspector, Timothy Reilly, to attend the compounding training in Chicago this October. NABP will also hold an Interactive Compliance Officer Forum this December and DHP intends to submit a travel request for a pharmacy inspector to attend. Ms. Juran stated that there are a couple possible dates for the upcoming 2014 NABP/AACP District I and II meeting that will be hosted by Virginia. Ms. Juran and Ms. Allen have been discussing with the four schools of pharmacy the option of hosting the meeting in Williamsburg. Ms. Juran and Ms. Allen will visit The Williamsburg Lodge in Colonial Williamsburg on September 13th for a tour.

NEW BUSINESS:

There was no new business.

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, 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 Shinaberry, second by Kozera)

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 Shinaberry, second by Kozera)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jennifer Wild Hoerrner, Pharmacist (motion by Warriner, second by Shinaberry)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Diana Rachel Jensen, Pharmacy Technician (motion by Warriner, second by Shinaberry)

FORMAL HEARING:

DAVID A. SHIMP
Pharmacist
License Number:
0202-209023

A formal hearing held in the matter of David A. Shimp to discuss his petition for reinstatement of his pharmacist license that was mandatorily suspended on November 16, 2012, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia.

Erin L. Barrett, Assistant Attorney General, was present as legal counsel for the Board. James E. Schliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Shimp appeared and was represented by Joel M. McCray, Esquire.

Patricia Sheehan, DHP Senior Investigator, testified on behalf of the Commonwealth.

David A. Shimp testified on his own behalf.

Closed Meeting: Ms. Shinaberry moved and 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 in the matter of David A. Shimp. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran and Erin L. Barrett attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

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

Decision: Ms. Stelly moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr.Schliessmann, amended by the Board and read by Ms. Barrett..

Ms. Stelly moved, and the Board voted unanimously, that Mr. Shimp's petition for the reinstatement of his pharmacist license be approved with Mr. Shimp providing the Board with evidence of five (5) additional continuing pharmacy education hours.

ADJOURN: With all business concluded, the Board adjourned at 4:30 p.m.

Jody H. Allen, Chairman

Date: _____

Caroline D. Juran, Executive Director

Date: _____

Attachment 1

Virginia Board of Pharmacy
COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Of the 34 items listed, I am in agreement with the majority but have a few comments on the following (The numbers refer to the items phrased as numbered questions). I need to state that this is my personal response as I am acting as an individual and not a representative of the USP. I will provide documentation as appropriate in my responses.

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

Response: The explanation is correct. However, one must keep in mind that most of the USP General Chapters were written for the pharmaceutical manufacturing industry, not for pharmaceutical compounding. Most of the chapters were written prior to the resurgence of pharmaceutical compounding so the terminology relates to manufacturing. However, we are now in the situation where we are trying to apply standards written for large scale manufacturers to small scale compounders. It will take time to get these chapters focused on the correct entities with reasonable standards for each.

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.

Response: Extended BUDs can be used in the absence of direct sterility testing as follows: Note the "program of sterility testing" statement below and the reference from <797> back to <795> regarding BUDs.

<795> PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS
STABILITY CRITERIA AND BEYOND-USE DATING
General Guidelines for Assigning Beyond-Use Dates

"In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for (1) Nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated; and for (2) sterile preparations for which a program of sterility testing is in place."

<797> STORAGE AND BEYOND-USE DATING
Determining Beyond-Use Dates

"...BUDS for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding-Nonsterile Preparations <795>*."

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>?

Response: If high risk batches of 25 or more are compounded, they must pass the sterility test. Batches less than 25 fall in the response to item #4 above.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

Sterility Testing

"All 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 that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs? *The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.

Response: The requirements to meet USP <71> Sterility Tests do not work unless larger quantities of preparation are compounded. For example:

<71> STERILITY TESTS

TEST FOR STERILITY OF THE PRODUCT TO BE EXAMINED

Number of Articles to be Tested

"Unless otherwise specified elsewhere in this chapter or in the individual monograph, test the number of articles specified in Table 3."

Table 3 for Parenteral Preparations includes the following:

Not more than 100 containers.	Test 10% or 4 containers, whichever is the greater.

Comment: In USP <71>, it appears that the minimum number required for testing is 4 containers, unless the volume in each is insufficient for the tests where the number will be increased to 8. If one is compounding less than 4 vials, it does not meet the requirements of this chapter. It is impractical in many cases to prepare additional vials to bring the number up to the minimum required for this chapter. For example, it is not feasible to prepare 5 vials so one can be dispensed and four can be used for sterility testing. One must remember that most of the chapters in the USP General Chapters were designed, developed and written for the pharmaceutical industry, where large volumes are prepared, not for compounding where only a few may be prepared. In addition, many of these CSPs are quite expensive and this prohibits compounding extra units. Also, as mentioned above, I don't know of any hospitals that would compound 5 intravenous admixtures so they could send four for sterility testing and one for the patient. We are in an awkward time when compounding has rapidly grown but many try to apply USP chapters to compounding pharmacy that have been written over the past 30-40 years for the pharmaceutical industry.

Loyd V. Allen, Jr., Ph.D., R.Ph.
Editor-in-Chief
International Journal of Pharmaceutical Compounding
Remington: The Science and Practice of Pharmacy
June 24, 2013

Attachment 2

BOP Presentation Sept 10, 2013

Motion: The pharmacist-in-charge (PIC) of the pharmacy that experiences either diversion or theft of Schedule II-VI drugs exceeding 100 oral tablets, or 100 usual oral liquid doses, or 25 ampules or vials shall be in violation of:
1. 18VAC 110-20-25 (6) Unprofessional Conduct: Failure to maintain adequate safe guards against diversion of controlled substances and,
2. Section 54.1-3434: Failure to provide safeguards against diversion of all controlled substances and,
3. 18VAC 110-20-110 (B) Pharmacy Permits: Failure to control all aspects of the practice of pharmacy and,
4. Section 54.1-3432: failure to supervise the pharmacy and it's personnel.
The pharmacist-in-charge shall be fined a minimum of $250 up to $5000 and reprimanded.

Authority:

54.1-3307 A/3
Page 49 "The Board's regulations shall include criteria for... Controls and safeguards against diversion of drugs"

2013 Experience:
Based on available on-line data for the first six months of 2013 the Board of Pharmacy took action against 9 pharmacists/technicians documenting the theft/diversion of over 13,000 doses of Schedule II-V drugs.

AT Least

Pharmacy and Drug Control Act Section 54.1

-3300/Page 44 Definitions

"Practice of Pharmacy":	Proper and safe storage and distribution of drugs.
"Supervision":	Direction and Control by a pharmacist of the activities of a technician.
--3307 A/3 Page 49	"The Board's regulations shall include criteria for... Controls and safeguards against diversion of drugs..."
--3404/E Page 66	"Whenever any registrant or licensee discovers a theft of any unusual loss of any controlled substance he shall immediately report theft/loss to the Board."
----3434 /page 88	"...The pharmacist in charge assumes full responsibility for the legal operation of the pharmacy"

(and) "The pharmacist to whom the permit is issued shall provide safeguards against diversion of all controlled substances."

Regulations Governing the Practice of Pharmacy 18 VAC

110-20-25 (6) (page 9)	Unprofessional Conduct is: Failing to maintain adequate safeguards against diversion of controlled substances.
110-20-110 (B) (page 18)	"The pharmacist in charge or pharmacist on duty shall control all aspects of the practice of pharmacy"*****
110-20-190 (A/1) (page 25)	"The prescription department enclosure.....shall be constructed to protect prescription drugs....from pilferage at all times...."
110-20-240 (A/1) (page 28)	"Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs....and reconciled at least monthly."
110-20-440 (A) (page 48)	"The PIC in a hospital pharmacy shall be responsible for security of all drugs...."
110-20-555 (12) (page 60)	"The PIC of the pharmacy providing services to nursing homes... is accountable for security of all drugs maintained in the automated drug dispensing system..."
110-20-570 (B) (page 61)	"Drugs maintained in infirmaries/first aid rooms...shall be secured in a locked storage area..."
110-20-580 (4) (page 62)	"Drugs maintained in humane society/animal shelter shall be stored in a secure, locked place...."
110-20-700 (A) (page 67)	"The supervising practitioner shall establish procedures for.....(drug) security..."

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Guidance Document

110-27 PIC Responsibilities
Opening/closing inventory and change of PIC inventory
Report theft and any unusual loss of drugs.

110-5 Theft or Loss of Drugs
Complete DEA-106 form.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
INFORMAL CONFERENCE COMMITTEE MINUTES

Monday, October 7, 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 9:06 a.m.
PRESIDING:	Empsy Munden, Committee Chair
MEMBERS PRESENT:	R. Crady Adams, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Jr., Deputy Executive Director Laura Z. Rothrock, Administrative Assistant Mykl D. Egan, DHP Adjudication Specialist
Jefferson Good Neighbor Pharmacy Permit No. 0201-004268	Ronald G. Davis, Pharmacist-in-Charge, appeared on behalf of Jefferson Good Neighbor Pharmacy to review allegations that Jefferson Good Neighbor Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 11, 2013, Notice.
Closed Meeting:	Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jefferson Good Neighbor Pharmacy. Additionally, he moved that Sammy Johnson, Laura Rothrock 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 Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and

unanimously voted to offer a Consent Order to Jefferson Good Neighbor Pharmacy.

(This Consent Order shall be effective upon endorsement by Jefferson Good Neighbor Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order).

The Medicine Shoppe #1500
Permit No. 0201-003405

Jeffery L. Dalton, Pharmacist-in-Charge, appeared on behalf of The Medicine Shoppe #1500 to review allegations that The Medicine Shoppe #1500 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 11, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of The Medicine Shoppe #1500. Additionally, he moved that Sammy Johnson, Laura Rothrock 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 Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to The Medicine Shoppe #1500.

(This Consent Order shall be effective upon endorsement by The Medicine Shoppe #1500 and the Board of the findings of fact, conclusions of law, and terms of the Order).

Nova Scripts Central, Inc.
Permit No. 0201-004153

Huyen B. Nguyen, Pharmacist-in-Charge, and Susan J. Morikawa, Executive Director, appeared on behalf of Nova Scripts Central, Inc. to review allegations that Nova Scripts Central, Inc. may have

violated certain laws and regulations governing the conduct of pharmacy as stated in the September 11, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Nova Scripts Central, Inc.. Additionally, he moved that Sammy Johnson, Laura Rothrock 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 Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Nova Scripts Central, Inc.

(This Consent Order shall be effective upon endorsement by Nova Scripts Central, Inc. and the Board of the findings of fact, conclusions of law, and terms of the Order).

Piedmont Infusion Services, Inc.
Permit No. 0201-004278

Jacob B. Patteron, Pharmacist-in-Charge, appeared on behalf of Piedmont Infusion Services, Inc. to review allegations that Piedmont Infusion Services, Inc. may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 30, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Piedmont Infusion Services, Inc.. Additionally, he moved that Sammy Johnson, Laura Rothrock 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 Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Piedmont Infusion Services, Inc.

(This Consent Order shall be effective upon endorsement by Piedmont Infusion Services, Inc. and the Board of the findings of fact, conclusions of law, and terms of the Order).

Home I.V. Care
Permit No. 0201-002399

Jennifer Tootle Screen, Pharmacist-in-Charge, Dr. Cathy G. Parks, General Manager, and staff members, Greg Dedrick and Terry McDonald, appeared on behalf of Home I.V. Care to review allegations that Home I.V. Care may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 11, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Home I.V. Care. Additionally, he moved that Sammy Johnson, Laura Rothrock 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 Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain

Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Home I.V. Care.

(This Consent Order shall be effective upon endorsement by Home I.V. Care and the Board of the findings of fact, conclusions of law, and terms of the Order).

Following this decision, Board Member Pratt Stelly arrived to participate in the next informal conference as Ms. Munden had recused herself. Mr. Adams presided in Ms. Munden's place.

Sentara Norfolk General Hospital Pharmacy
Permit No. 0201-001014

Donald P. Durkee, Pharmacist-in-Charge, appeared on behalf of Sentara Norfolk General Hospital Pharmacy to review allegations that Sentara Norfolk General Hospital Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 30, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Adams, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Sentara Norfolk General Hospital Pharmacy. Additionally, she moved that Sammy Johnson, Laura Rothrock 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. Stelly, and duly seconded by Mr. Adams, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Sentara Norfolk General Hospital Pharmacy.

(This Consent Order shall be effective upon

endorsement by Sentara Norfolk General Hospital Pharmacy 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 3:15 p.m.

Empsy Munden
Chair

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

MINUTES OF SUMMARY SUSPENSION

Tuesday, October 15, 2013
Commonwealth Conference Center
Second Floor
Board Room 2

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 the Board of Pharmacy ("Board") was called to order at 9:45 a.m.

PRESIDING: Jody H. Allen, Chair

MEMBERS PRESENT:
R. Crady Adams
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT:
Caroline Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Erin Barrett, Assistant Attorney General
Corie Tillman Wolf, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven (7) members participating and three (3) unable to participate, a quorum of the Board of Pharmacy ("Board") was established.

ERIKA M. REYNOLDS
Pharmacy Technician
Registration # 0230-007005

Corie T. Wolf, Assistant Attorney General, presented a summary of the evidence in this case for the panel to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Closed Meeting: The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Cathy Reiniers-Day, Caroline D. Juran, Eusebia Joyner and Erin Barrett attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (Motion by D. Kozera, second by C. Adams).

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:

The Board voted unanimously in favor of the motion that, according to the evidence presented the continued practice by Erika M. Reynolds as a pharmacy technician poses a substantial danger to the public; and therefore, Ms. Reynolds' registration to practice as a pharmacy technician be summarily suspended. (Motion by J. Allen and second by C. Adams).

The Board unanimously voted that, in lieu of a hearing, a Consent Order shall be offered to Ms. Reynolds for the indefinite suspension of her registration for a period of not less than two years. (Motion by D. Kozera, second by C. Adams).

LISA MARIE BARTLETT
Pharmacist
License Number 0202-211858

Corie T. Wolf, Assistant Attorney General, presented a summary of the evidence in this case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Closed Meeting:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Cathy Reiniers-Day, Caroline D. Juran, Eusebia Joyner and Erin Barrett attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (Motion by E. Shinaberry, second by R. Rhodes).

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.

The Board voted unanimously in favor of the motion that, according to the evidence presented the continued practice by Lisa Marie Bartlett as a

pharmacy technician poses a substantial danger to the public; and therefore, Ms. Bartlett's registration to practice as a pharmacy technician be summarily suspended. (Motion by Ms. E. Shinaberry and second by R. Rhodes).

The Board unanimously voted that, in lieu of a hearing, a Consent Order shall be offered to Ms. Bartlett for the indefinite suspension of her registration for a period of not less than two years. (Motion by P. Stelly, second by D. Kozera).

Adjourn:

With all business concluded, the meeting adjourned at 10:45 a.m.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

MINUTES OF A PANEL FORMAL HEARING

Tuesday, October 15, 2013
Commonwealth Conference Center
Second Floor
Board Room 2

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 10:45 a.m.

PRESIDING: Jody H. Allen, Chair

MEMBERS PRESENT:
R. Crady Adams
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Erin Barrett, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven (7) members participating and three unable to participate, a Panel of the Board of Pharmacy ("Board") was established.

CHRISTINE A. KROEL
Registration # 0230-002385

A formal hearing was held in the matter of Christine A. Kroel, following the summary suspension of her pharmacy technician registration on August 26, 2013, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Kroel was not present at the hearing. The Board proceeded with the hearing in Ms. Kroel's absence as the Notice of Formal Hearing dated August 26, 2013, was mailed to her legal address of record, both by regular and certified mail. Ms. Allen ruled that adequate notice was provided to Ms. Kroel.

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

Kevin Schwar, Asset Protection Division Manager, Rite Aid Pharmacy; and Patricia Harte-Byers, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Shinaberry and duly seconded by Mr. Adams, 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 Christine A. Kroel. Additionally, he moved that Cathy Reiniers-Day, Caroline D. Juran, Eusebia Joyner and Erin Barrett 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. Kozera and duly seconded by Ms. Shinaberry, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Ms. Barrett.

Upon a motion by Mr. Kozera and duly seconded by Mr. Adams, the panel voted 7-0 that Ms. Kroel's registration to practice as a pharmacy technician shall be revoked.

RACHAEL N. TESTER
Registration # 0230-009883

A formal hearing was held in the matter of Rachael N. Tester, following the summary suspension of her pharmacy technician registration on August 26, 2013, to discuss allegations that she 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 Mykl Egan, DHP Adjudication Specialist.

Jason S. Lotts, Loss Prevention Specialist, CVS/pharmacy #7561; and Kimberly B. Lynch, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Shinaberry and duly seconded by Ms. Stelly, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia ("Code"), for the purpose of consideration and discussion of medical records of Rachael N. Tester that are excluded from the Freedom of Information Act of § 2.2-3705(A)(5) of the Code of Virginia. Additionally, she moved that Cathy Reiniers-Day, Caroline D. Juran, Eusebia Joyner and Erin Barrett 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.

Closed Meeting:

Upon a motion by Ms. Shinaberry and duly seconded by Ms. Stelly, 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 Rachael N. Tester. Additionally, she moved that Cathy Reiniers-Day, Caroline D. Juran, Eusebia Joyner and Erin Barrett 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. Kozera and duly seconded by Mr. Adams, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Ms. Barrett.

Upon a motion by Mr. Kozera and duly seconded by Mr. Rhodes, the panel voted 7-0 that Ms. Tester's registration to practice as a pharmacy technician shall be continued on indefinite suspension with the suspension stayed contingent upon her entering into a contract with the Health Practitioners Monitoring Program.

Adjourn: With all business concluded, the meeting adjourned at 3:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Jody H. Allen, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Thursday, October 17, 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:	Ellen B. Shinaberry, Committee Chair
MEMBERS PRESENT:	Pratt P. Stelly, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
HARRY M. BROOKS Registration No. 0230-005946	Harry M. Brooks appeared to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 17, 2012, Notice.
Closed Meeting:	Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, 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 Harry M. Brooks. 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. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order with terms and conditions due to Mr. Brooks' failure to comply with the continuing education requirements.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Brooks, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Brooks 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.

HAROLD T. WILLIS
License No. 0202-005147

Harold T. Willis appeared to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 20, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, 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 Harold T. Willis. 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. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to Mr. Willis for a reprimand due to the lack of drug security.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Willis, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Willis 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 2:35 p.m.

Ellen B. Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, November 7, 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 on November 7, 2013, at 9:30 a.m., to consider the summary suspension of the registration of Megan E. Griffin to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Jody H. Allen, Chair

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

MEMBERS ABSENT:
David C. Kozera
Dinny Li
Robert M. Rhodes
Ellen B. Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Mykl Egan, DHP Adjudication Specialist
Charis Mitchell, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General

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.

MEGAN E. GRIFFIN
Registration No. 0230-020082

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

Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Megan E. Griffin poses a substantial danger to the public; and therefore, the registration of Ms. Griffin shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Griffin for the indefinite suspension of her registration for a period of not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at 10:00 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Jody H. Allen, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL & INFORMAL CONFERENCE COMMITTEE

Tuesday, November 12, 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 an Informal Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	Ellen B. Shinaberry, Committee Chair
MEMBERS PRESENT:	Robert M. Rhodes, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
CYRUS KIRKPATRICK PHARMACY Permit No. 0201-002729	Robert S. McClelland, Pharmacist-in-Charge; Elizabeth Moody, Pharmacy Technician; and Aubrey S. Clay, Jr., Pharmacist, appeared on behalf of Cyrus Kirkpatrick Pharmacy to review allegations that Cyrus Kirkpatrick Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 10, 2013, Notice.
Decision:	Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, 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 Cyrus Kirkpatrick Pharmacy. Additionally, he 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 Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Cyrus Kirkpatrick Pharmacy, for a monetary penalty in the amount of $ 7,500. (This Consent Order shall be effective upon endorsement by Cyrus Kirkpatrick Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order).
J & F INTERNATIONAL D/B/A ALEXANDRIA COMPOUNDING PHARMACY Permit No. 0201-001707	Farzana Kennedy, Pharmacist-in-Charge; Yelena Kleyner, Pharmacy Technician; and Hunter Jamerson, their attorney, appeared on behalf of J & F International d/b/a Alexandria Compounding Pharmacy to review allegations that J & F International d/b/a Alexandria Compounding Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 10, 2013, Notice.
Decision:	Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, 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 J & F International d/b/a Alexandria Compounding Pharmacy. Additionally, he 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 Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to J & F International d/b/a Alexandria Compounding Pharmacy, for a monetary penalty in the amount of $ 10,000.

(This Consent Order shall be effective upon endorsement by J & F International d/b/a Alexandria Compounding Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order).

KARE PHARMACY
Permit No. 0201-002103

Prakash K. Suthar, Pharmacist-in-Charge, appeared on behalf of Kare Pharmacy to review allegations that Kare Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 10, 2013, Notice.

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, 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 Kare Pharmacy. Additionally, he 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 Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Kare Pharmacy, for a monetary penalty in the amount of $ 5,750.

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

THE WELLNESS PHARMACY
Permit No. 0201-003469

Bruce Kowiatek, Pharmacist-in-Charge; Russell T. Lederhouse, owner; and Margaret Hardy, their Attorney, appeared on behalf of The Wellness Pharmacy to review allegations that The Wellness

Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 1, 2013, Notice.

Decision: Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, 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 The Wellness Pharmacy. Additionally, he 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 Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to The Wellness Pharmacy, for a monetary penalty in the amount of $ 18,250.

(This Consent Order shall be effective upon endorsement by The Wellness Pharmacy 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 6:20 p.m.

Ellen B. Shinaberry
Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board **as of November 27, 2013**

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Proposed - *At Secretary's Office for 846 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Continuous quality improvement programs [Action 3496] Proposed - *Register Date: 11/18/13* *Comment period: 11/18/13 to 1/17/14* *Emergency regulations expired 9/30/13*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 202 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Modifications to requirements for automated dispensing devices for less burdensome process [Action 3578] Final - *At Governor's Office for 36 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Less restrictive and burdensome record-keeping for on-hold prescriptions [Action 3451] Final - *At Governor's Office for 36 days*
[18 VAC 110 - 40]	Regulations Governing Collaborative Practice Agreements	Conformity to changes in the Code [Action 4101] Final - *At Attorney General's Office for 34 days*

MEMORANDUM

TO: Drug Enforcement Administration, Department of Justice

FROM: Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

DATE: December 12, 2013

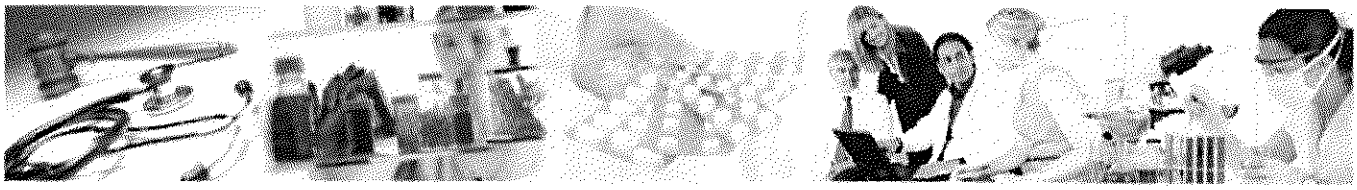
RE: Comment on Proposal to place tramadol into Schedule IV

Docket No. DEA-351

At its meeting on December 12, 2013, the Virginia Board of Pharmacy voted to support the placement of tramadol into Schedule IV by the Drug Enforcement Administration (DEA).

The Board supported legislative proposals in Virginia in 2010, 2011, and 2013 to place tramadol into Schedule IV due to concerns with the potential for abuse, diversion and illicit use. Additionally, placement of tramadol into Schedule IV would have required dispensers of drugs to report dispensing information to the Virginia Prescription Monitoring Program (PMP). Two bills introduced in the 2010 Session of the Virginia General Assembly were carried over to 2011 in Committee, where they were left. Similar bills introduced in 2012 and 2013 were defeated in the Appropriations Committee because of the potential fiscal impact. Chapter 3 of the Acts of Assembly of 2012, Special Session I, requires the Virginia Criminal Sentencing Commission to assign a minimum fiscal impact of $50,000 if the estimated amount of the necessary appropriation cannot be determined for periods of imprisonment in state adult correctional facilities.

Other bills in recent years that simply conform drug scheduling in the Virginia Drug Control Act to federal scheduling have successfully been approved. Therefore, the Virginia Board of Pharmacy urges DEA to place tramadol into Schedule IV.



Rules - 2013

[Federal Register Volume 78, Number 213 (Monday, November 4, 2013)]
[Proposed Rules]
[Pages 65923-65932]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2013-25933]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-351]

Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to place the substance 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol (the term "isomers" includes the optical and geometric isomers) into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.

DATES: Interested persons may file written comments on this proposal pursuant to **21 CFR 1308.43**(g). Electronic comments must be submitted, and written comments must be postmarked, on or before January 3, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (**21 U.S.C. 811**)," **21 CFR 1300.01**, may file a request for hearing pursuant to **21 CFR 1308.44** and in accordance with **21 CFR 1316.45** and **1316.47**. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 4, 2013.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-351" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the on-line instructions at that site for submitting comments. An electronic copy of this document and supplemental information to this proposed rule are also available at the http://www.regulations.gov Web site for easy reference. Paper comments that duplicate electronic submissions are not necessary. All comments submitted to http://www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 598-6812.

SUPPLEMENTARY INFORMATION: *Posting of Public Comments:* Please note that comments received in response to this NPRM are considered part of the public record and will be made available for public inspection and posted at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made public, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available.

Comments containing personal identifying information and confidential business information identified and located as set forth above will be made available in redacted form. The Freedom of Information Act (FOIA) applies to all comments received. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the FOR FURTHER INFORMATION CONTACT paragraph, above.

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Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

Pursuant to the provisions of the CSA (**21 U.S.C. 811**(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA) (5 U.S.C. 551-559). **21 CFR 1308.41-1308.45**, and **21 CFR part 1316** subpart D. In accordance with **21 CFR 1308.44**(a)-(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." **21 CFR 1300.01**. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and **1316.47** or **1316.48**, as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be

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heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and **1316.49**, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to **21 U.S.C. 811**(a), the purpose and subject matter of a hearing is restricted to "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] 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. * * *" Requests for hearing, notices of appearance at the hearing, and waivers of an opportunity for the hearing or to participate in the hearing should be submitted to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, but they are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purposes of this action. **21 U.S.C. 801-971**. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), **parts 1300 to 1321**. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

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 schedules of controlled substances established by Congress 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 the DEA, who has further delegated this authority to the Deputy Administrator of the DEA. 28 CFR 0.104.

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 HHS; or (3) on the petition of any interested party. **21 U.S.C. 811**(a). This proposed action is based on a recommendation from the Assistant Secretary for Health of the HHS and on an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.\1\

\1\ See infra footnote 2.

Background

Tramadol is an opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the "M1" metabolite (O-desmethyltramadol). Since March 1995, tramadol has been available as a non-controlled and centrally acting opioid analgesic under the trade name ULTRAM[supreg] approved by the Food and Drug Administration (FDA) in the United States. Subsequently, the FDA approved generic, combination, and extended release products of tramadol.

Because of its chemical structure, 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol can exist as different isomeric forms. Thus, various prefixes can be associated with the name. Some examples of these prefixes include dextro, levo, d, l, R, S, cis, trans, erythro, threo, (+), (-), racemic, and may include combinations of these prefixes sometimes with numerical designations. Any such isomer is, in fact, 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol. Tramadol is typically formulated as a racemic mixture identified as ()-cis-2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol hydrochloride.\2\

\2\ For simplicity's sake, from this point forward in the document, "tramadol" is used to refer to 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms.

Proposed Determination To Schedule Tramadol

The DEA received four petitions between October and November 2005 requesting that tramadol be controlled as a scheduled substance under the CSA. Three of these petitions specifically requested the placement of tramadol into Schedule III; the remaining petition did not specify a schedule for control. One of the petitioners stated that "tramadol has significant abuse potential, consistent with its pharmacology. This abuse has significant public health policy implications."

Pursuant to **21 U.S.C. 811**(b) of the CSA, the DEA gathered the necessary data on tramadol and, on April 25, 2007 submitted it to the Assistant Secretary of the HHS with a request for a scientific and medical evaluation and the Secretary's recommendation as to whether or not tramadol should be added as a controlled substance, and, if so, in which schedule. On September 16, 2010, the HHS provided to the DEA a written scientific and medical evaluation and scheduling recommendation entitled "Basis for the Recommendation to Schedule Tramadol in Schedule IV of the Controlled Substances Act." In this recommendation, the HHS presented its eight-factor analysis as required under 21 U.S.C. 811(b), and recommended that

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tramadol be added to Schedule IV of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS and all other relevant data, and completed an eight-factor review document pursuant to **21 U.S.C. 811**(c) in February 2011. Included below is a brief summary of each factor as analyzed by the HHS in its 2010 transmittal and the DEA in its 2011 analysis, and as considered by the DEA in its proposed scheduling decision. Please note that both the DEA and HHS analyses are available in their entirety under "Supporting and Related Material" of the public docket for this rule at http://www.regulations.gov under docket number "DEA-351." Full analysis of, and citations to, information referenced in the summary may also be found in the supporting material.

1. The Drug's Actual or Relative Potential for Abuse: Data gathered by the DEA and HHS indicate that since the initial marketing of tramadol in 1995, tramadol has been, and currently is, abused for its opioid effects. The DEA has considered all relevant data and found that:

a. Individuals Are Taking Tramadol in Amounts Sufficient To Create a Hazard to Their Health or to the Safety of Other Individuals or to the Community

Published case reports, case series, and data from databases such as the Drug Abuse Warning Network (DAWN) suggest that individuals are taking tramadol in amounts sufficient to create a hazard to their health, to the safety of other individuals, and to the community. Tramadol abuse is associated with serious adverse events including death, drug dependence, drug withdrawal symptoms, seizures, serotonin syndrome, and other serious medical problems.

DAWN is a database, managed by the Substance Abuse and Mental Health Services Administration (SAMHSA), which collects data on drug-related emergency department (ED) visits from a nationally representative sample of hospitals in the United States and a selection of metropolitan areas. The HHS reviewed and analyzed DAWN data from 2004 through 2008 and found that the estimated annual non-medical \3\ Emergency Department (ED) visits from non-medical use of tramadol and its combinations (hereinafter "tramadol/combinations") continually increased from 4,849 ED visits to 11,850 ED visits. The DEA also evaluated more recent DAWN data and found that this increasing trend for tramadol continued in 2009 and 2010 (15,349 and 16,251 ED visits, respectively).

\3\ As defined by the DAWN glossary, non-medical use of pharmaceuticals includes prescription and over-the-counter pharmaceuticals in ED visits that are of the following types of cases:

Overmedication--Patient took too much of his/her prescription medication.

Malicious poisoning--Drug use in which the patient was administered a drug by another person for a malicious purpose.

Other--This category includes all drug-related ED visits that could not be assigned into any of the other classifications used by DAWN (suicide, attempt, seeking detox, alcohol only (under 21), adverse reaction, overmedication, malicious poisoning, and accidental ingestion).

Non-medical use may involve pharmaceuticals alone or pharmaceuticals in combination with illicit drugs or alcohol.

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The American Association of Poison Control Centers (AAPCC) manages the National Poison Data System (NPDS), which is the only near real-time comprehensive poisoning surveillance database in the United States. The NPDS collects information from the poison centers across the United States. The HHS reviewed the NPDS data and found that the number of case mentions of human toxic exposures to tramadol during 2004 through 2008 increased annually from 3,769 to 9,623. The DEA reviewed the more recent NPDS data and found that in 2009, 2010, and 2011, the number of reported tramadol poison exposures, alone and in combination with other drugs, totaled 10,255; 11,225; and 12,424, respectively. Of these totals, intentional exposures to tramadol alone (i.e., exposures not including tramadol/combinations or tramadol in combination with any other substances) were 2,677; 2,867; and 3,170, resulting in four deaths in 2009, three deaths in 2010, and six deaths in 2011.

b. There Is a Significant Diversion of Tramadol From Legitimate Drug Channels

The National Forensic Laboratory Information System (NFLIS) is a DEA database that collects scientifically verified data on analyzed samples in state and local forensic laboratories. It also includes data from the System to Retrieve Information from Drug Evidence (STRIDE), which includes data on analyzed samples from DEA laboratories. The data show that for each of the years from 2000 through 2012, tramadol was present in drug exhibits seized in the course of law enforcement activity.\4\ The tramadol exhibits seized by law enforcement involving drug abuse indicate the diversion of tramadol in the United States \5\ Tramadol exhibits increased from a total of 82 in 2000 to 1,806 in 2012 (NFLIS data). In 2010, this number was greater than the number of exhibits shown to contain pentazocine (96, Schedule IV), but less than the number of hydrocodone (45,627, Schedule III), codeine (3,679, Schedules II, III, V), and buprenorphine (10,167, Schedule III) exhibits (NFLIS data). The number of tramadol exhibits is similar to that of propoxyphene (1,320, Schedule IV) (2010 NFLIS data). However, the reduced number of propoxyphene exhibits (561) in 2011 is significantly less than that of tramadol (1,704) due to the FDA's recommendation to withdraw propoxyphene from the United States market.

\4\ Because the primary focus of law enforcement agencies (with respect to drugs) is on investigating the unlawful distribution of drugs, the incidents in which tramadol has been seized in the course of law enforcement investigations supports a finding that the drug is being abused and/or diverted from legitimate channels. Moreover, because tramadol is not controlled in most states there is reason to believe that many laboratories may not report those incidents in which they have identified a substance as tramadol. This suggests that tramadol would likely rank substantially higher in NFLIS data were it controlled nationally.

\5\ While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted or abused. 76 FR 77330, 77332, Dec. 12, 2011.

A post-marketing study published in 2002 and cited by the HHS's review document reported that among 140 health care professionals who had at least one positive tramadol urine specimen, 87 cases were associated with illegal prescriptions for obtaining tramadol. Another study referred to in the HHS review noted that from January 2002 through March 2004 there were 72 cases involving the diversion of tramadol from all 50 state law enforcement agencies. However, the number of tramadol diversion cases was less than the number of diversion cases associated with hydrocodone and oxycodone.

c. Individuals Are Taking Tramadol on Their Own Initiative Rather Than on the Basis of Medical Advice From a Practitioner Licensed by Law to Administer Such Drugs

The DEA's evaluation found that current evidence indicates that individuals take tramadol on their own initiative without medical consultation. This evidence includes case reports of abuse and dependence on tramadol in the medical literature, national drug abuse monitoring systems, and epidemiological data (DAWN, NFLIS, STRIDE, AAPCC, and the National Survey on Drug Use and Health (NSDUH)).

DAWN data show that from 2004 to 2010, the national annual estimates of ED visits related to non-medical use or

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abuse \6\ of tramadol/combinations increased from 4,849 to 16,251. Upon normalization of the number of non-medical ED visits relative to 100,000 prescriptions dispensed, the rate of ED visits for tramadol/ combinations was found similar to the rates for propoxyphene.

\6\ Since 2004, DAWN has defined "drug misuse or abuse" as a group of ED visits including all visits associated with the non-medical use of pharmaceuticals.

The NSDUH, operated by SAMHSA, provides information on the non-medical use of drugs in the United States population age 12 and older and its database provides annual estimates on the lifetime non-medical use of opioids and pain relievers. The estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 994,000 in 2002 to 2,614,000 in 2011.

The NPDS from AAPCC reported that the number of tramadol exposures increased each year between 2004 (3,769 cases) and 2011. In 2011, the number of reported tramadol poison exposures totaled 12,424. Of these total poison exposures in 2011, the intentional exposures to tramadol alone (i.e., not tramadol/combinations or in combination with other substances) were 3,170--six of which resulted in death. These findings indicate that tramadol poses a significant threat to the public health.

d. Tramadol is so Related in Its Action to a Drug or Other Substance Already Listed as Having a Potential for Abuse To Make It Likely That It Will Have the Same Potential for Abuse as Such Substance, Thus Making It Reasonable To Assume That There May Be Significant Diversions From Legitimate Channels, Significant Use Contrary to or Without Medical Advice, or That It Has a Substantial Capability of Creating Hazards to the Health of the User or to the Safety of the Community

According to the HHS review, tramadol shares many similar pharmacological activities with some opioids scheduled under the CSA. As such, the abuse potential of tramadol would be expected to be related to its opioid properties. As a result, tramadol would be expected to be diverted from legitimate sources, be used without medical supervision, and consequently be a safety concern to individuals and the community.

The opioid activity of tramadol is primarily due to the "M1" metabolite. Compared to other opioids, tramadol showed a longer onset of action due to accumulation of the active metabolite and its effects include analgesia, respiratory depression, miosis, cough suppression, and inhibition of bowel motility. Preclinical studies demonstrate that tramadol, like other opioids in Schedules I through IV, exhibits complete generalization to morphine and is able to produce some reinforcing effects. Repeated administration of tramadol in animals caused dependence development, evidenced by a withdrawal syndrome similar in intensity to pentazocine (Schedule IV) or propoxyphene (Schedule IV). Human studies reveal that tramadol produces some reinforcing subjective effects at high doses. A similar dose response pattern at high doses with propoxyphene to produce reinforcing subjective effects was also observed. Thereby, propoxyphene may serve as an appropriate comparator drug for tramadol with respect to generating reinforcing effects. According to the HHS review, several studies examining chemical abuse potential suggest that the subjective reinforcing effect of tramadol is less than that of Schedule II opioids and more comparable to that of propoxyphene.

In summary, the abuse potential of tramadol is similar to that of substances in Schedule IV (such as propoxyphene) of the CSA. The accumulated information demonstrates that individuals take tramadol non-medically and in amounts sufficient to create a hazard to their health. Tramadol is diverted from legitimate sources and produces effects similar to other CSA-controlled opioids known to have an abuse potential. Furthermore, the available information regarding reinforcing effects and drug dependence shows that the abuse potential of tramadol is less than that of morphine (Schedule II), oxycodone (Schedule II), or buprenorphine (Schedule III), but similar to that of propoxyphene (Schedule IV). Additionally, epidemiological data also support an abuse potential for tramadol that is similar to substances in Schedule IV of the CSA. These data suggest that tramadol has an abuse potential warranting control under the CSA.

The DEA and HHS believe that an evaluation of the accumulated information demonstrates that the indicators of a drug's potential for abuse, as described in the legislative history of the CSA, are present for tramadol. Obtained or diverted from legitimate sources, individuals take tramadol in the absence of medical supervision and in amounts sufficient to create a hazard to their health. Tramadol produces effects similar to opioids known to have an abuse potential and that are controlled under the CSA.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known: The DEA and HHS recognize tramadol as an opioid analgesic with monoaminergic activity that contributes to its analgesic effects. The M1 metabolite of tramadol contributes to its opioid effects and may be the cause of the delayed and prolonged activity associated with tramadol administration. Tramadol can block the reuptake of norepinephrine and serotonin, effects also produced by such opioids as meperidine (Schedule II), methadone (Schedule II), and levorphanol (Schedule II).

Preclinical animal studies found that tramadol demonstrated a dose-related anti-nociceptive effect. Its analgesic effects were compared to other Schedule III and IV opioid analgesics. In clinical trials for treatment in human subjects, tramadol was less effective than hydrocodone/acetaminophen (Schedule III), but displayed an analgesic effect similar to that of pentazocine (Schedule IV), and superior or similar to the propoxyphene/acetaminophen combination (Schedule IV) in relieving postoperative pain.

Tramadol produces abuse liability-related effects in various animal models and humans. It has been self-administered by monkeys, producing reinforcing effects which qualitatively show a similarity to opioids. In a drug discrimination study using rats, tramadol was shown to produce systematic generalization to morphine. Similar to other opioids in Schedules II through IV, tramadol fully substituted for discriminative effects of morphine and morphine fully substituted for tramadol. Drug

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Collectively, data from DAWN, NSDUH, NFLIS, STRIDE, and AAPCC-NPDS databases demonstrate the misuse, abuse, and diversion of tramadol in the United States. With respect to the rates of non-medical ED visits found in DAWN, the number of NFLIS exhibits, and the increasing rates of AAPCC's NPDS reporting, tramadol data most closely resembles that of propoxyphene (Schedule IV).

5. The Scope, Duration, and Significance of Abuse: The scope, duration, and significance of tramadol abuse is evidenced by findings of national monitoring databases for drug abuse, review of studies of abuse potential, and clinical case reports. The HHS concluded its 15 years of post-marketing epidemiologic abuse-related data in the scientific literature and from the adverse events reporting system (AERS) since tramadol's commercial availability in the United States. The case reports describe abnormal behavior that demonstrates an addiction liability of tramadol: drug craving, increasing the tramadol dose, performing self-injury in order to be prescribed more tramadol, taking high doses despite adverse effects that result, and visiting multiple physicians in order to obtain more prescriptions for tramadol. Approximately 15 years of post-marketing history now show that tramadol can be, and is being, abused both in the United States and other countries.

Clinical case reports in the medical literature provide information on patterns of tramadol abuse when prescribed for clinical pain management. The case reports listed by the HHS review describe abuse of tramadol for its euphorigenic and sedating effects. The depicted behavior illustrates an addiction to tramadol: Drug craving, increasing the tramadol dose, inflicting self-injury in order to be prescribed more tramadol, taking high doses despite adverse effects that result, and visiting multiple doctors in order to obtain more prescriptions for tramadol. These reports provide information on characteristics and patterns of actual tramadol abuse with the development of dependence. Development of iatrogenic addiction to tramadol due to medical treatments is also reported.

The NSDUH data, discussed in detail in Factor 4, also provides evidence of the non-medical use of tramadol. According to the NSDUH data, the estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 994,000 in 2002 to 2,614,000 in 2011. For each year from 2002 to 2007, the number of individuals reporting either lifetime non-medical use or past-year non-medical use of tramadol was lower than the number of that of hydrocodone or oxycodone. The estimated number of individuals who have used tramadol products non-medically at least once in their lifetime increased from 2008 to 2011, but these numbers for tramadol are still lower than that of oxycodone (Schedule II) and hydrocodone combination products (Schedule III).

According to DAWN data, in 2010, an estimated 16,251 ED visits nationally were for non-medical use of tramadol. There is an increasing annual trend of non-medical ED visits from 2004 through 2010. Furthermore, the HHS reviewed the national estimates of ED visits related to non-medical use and to rates of these visits per 100,000 prescriptions from 2004 to 2008, and found tramadol most closely compares to propoxyphene (Schedule IV) and to codeine (Schedules II, III, V).

Collectively, the data shows that tramadol has less abuse potential than other pure mu-receptor agonists currently controlled in Schedule II. As evaluated by the HHS and the DEA, the DAWN data indicates tramadol most closely compares to propoxyphene (Schedule IV) and codeine (Schedules II, III, V). The NSDUH data from 2002 to 2007, cited by the HHS, also indicates the number of individuals reporting non-medical use of tramadol was lower than that of individuals using hydrocodone combination products (Schedule III) and oxycodone (Schedule II) products, suggesting an abuse potential less than that of Schedule III.

Tramadol's similarity to other controlled opioids and clear evidence of significant non-medical use and abuse, accompanied by serious adverse events, indicate that tramadol has sufficient abuse potential and incidence of drug dependence and addiction to warrant control as a Schedule IV controlled substance under the CSA.

6. What, if any, Risk There is to the Public Health: The DEA analysis indicates that there are numerous risks to the public health that may result from tramadol abuse. Tramadol and its M1 metabolite are opiate agonists devoid of opioid antagonist activity. Adverse effects occurring with tramadol are consistent with adverse effects associated with other opioids. The incidence of reported adverse effects increased as the time of tramadol therapy increased. The overall incidence rates of adverse effects of tramadol were similar to that of codeine containing drugs. Other adverse effects associated with tramadol included seizures, serotonin syndrome, and respiratory depression. Case studies of tramadol overdoses from United States poison centers reported that tramadol overdoses presented multiple systematic symptoms ranging from cardiovascular toxicity to significant neurologic toxicity including lethargy, nausea, tachycardia, agitation, seizures, coma, hypertension, and respiratory depression. The toxic mechanism of tramadol overdose is closely related to its [micro]-opioid receptor activity and its monoamine oxidase inhibition activity.

Information from the DAWN database shows that the rates of ED visits due to non-medical use of tramadol have been

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similar to that of propoxyphene (Schedule IV) but lower than that of Schedule II and III opioids from 2004 to 2008. The HHS reviewed DAWN data and found that a total of 395 tramadol abuse-related deaths were reported to DAWN from 1997 to 2002 in selected areas. The result demonstrates a risk to the public health associated with the non-medical use of tramadol that is similar to that of propoxyphene (Schedule IV).

An increased number of exposure and death cases were reported by the AAPCC's NPDS database. It showed that from 2004 to 2011, annual tramadol exposures increased from 3,769 to 12,424. The HHS found that tramadol ranked third behind hydrocodone combination products (Schedule III) and oxycodone (Schedule II) in terms of the number of poison case mentions of opioids in 2007 and 2008. Over this period, the rates of case mentions per 100,000 prescriptions for tramadol increased from 22 to 37. In addition, the rate of tramadol case mentions was lower than for oxycodone (Schedule II), morphine (Schedule II), and methadone (Schedule II). For the years 2004, 2005, and 2006, the rates of tramadol case mentions were similar to that of propoxyphene (Schedule IV).

The labeling information approved by the FDA states that tramadol in excessive doses, alone or in combination with other central nervous system depressants, including alcohol, is a cause of drug-related deaths. Deaths associated with tramadol were also documented in the medical literature. Other reports document tramadol as a contributing factor to deaths in combination with other drugs such as, but not limited to, benzodiazepines, serotonergic drugs, and other antidepressants. The annual number of tramadol-related deaths reported by medical examiners in the DAWN database gradually increased from 1997 to 2004.

Reports of tramadol associated deaths from the Florida Department of Law Enforcement (FDLE) were also reviewed by the HHS and it was found the number of deaths involving tramadol increased from 106 in 2003 to 235 in 2008. According to FDLE's data, tramadol-related deaths were higher than heroin-related deaths between 2005 and 2008. For each of those years, the number of deaths involving tramadol was less than the number of deaths involving hydrocodone combination products (Schedule III), fentanyl (Schedule II), morphine (Schedule II), oxycodone (Schedule II), methadone (Schedule II), and propoxyphene (Schedule IV). The DEA reviewed the data for the years 2009 to 2011, and found that tramadol-related deaths continued to increase. There were 268 tramadol-related deaths in 2009, 275 tramadol-related deaths in 2010, and 379 tramadol-related deaths in 2011.

In summary, the collected data from a number of sources indicate that tramadol presents risks to the public health and, as such, supports the scheduling of tramadol. The DAWN, AAPCC, and FDLE data suggest a lower schedule for tramadol than Schedule III.

7. Its Psychic or Physiological Dependence Liability: The HHS reviewed available information from pre-clinical and clinical studies and found that repeated dosing with tramadol resulted in dependence development, and withdrawal syndromes resulted from termination of tramadol treatment. Additionally, medical literature also documents numerous case reports of physiological and physical dependence to tramadol.

Preclinical studies using monkeys and rats found that the tested animals displayed withdrawal signs after the termination of tramadol. Tramadol's potential to produce physical dependence was evidenced by naloxone precipitated withdrawal in observed animals. The results also supported that tramadol produced a degree of physical dependence similar to that of propoxyphene (Schedule IV). Infusion of tramadol in rats found that the total withdrawal scores of tramadol were lower than that of morphine (Schedule II) following naloxone administration. By comparing physical dependence development resulting from repeated subcutaneous administration of either morphine or tramadol to mice, another study concluded that tramadol produced a lesser degree of physical dependence than morphine. These findings suggest that tramadol can produce mild to moderate levels of physical dependence and the degree of dependence of tramadol is less than that of Schedule II, but similar to that of Schedule IV drugs such as pentazocine and propoxyphene.

A number of clinical studies examined the ability of tramadol to substitute for other opioids in individuals who are opioid dependent. A study compared the effectiveness of tramadol versus buprenorphine (Schedule III) in the treatment of opiate withdrawal and found that tramadol and buprenorphine effectively managed acute opioid withdrawal syndrome displayed by patients with mild to moderate addiction to heroin. Another study compared the use of tramadol to that of clonidine (not controlled under the CSA) for management of acute heroin (Schedule I) withdrawal and found that tramadol was more effective in managing withdrawal than clonidine. One study revealed a cross dependence development between tramadol and morphine (Schedule II) in opioid-dependent adults. A modest suppression of opioid withdrawal produced by tramadol was also reported in subjects with a mild to moderate degree of opioid physical dependence and this finding was also supported by several published case reports.

According to the HHS review, as of September 9, 2009, "Withdrawal symptoms may occur" was documented in the "Warning" section of the label for a tramadol containing product. Combining studies of cross dependence, tramadol produces a modest suppression of withdrawal in subjects dependent on other opioids and this suppression appears less than that produced by morphine (Schedule II) or buprenorphine (Schedule III).

In conclusion, the HHS states that collectively the data shows tramadol can produce a modest level of physical dependence, with the studies suggesting a degree of physical dependence development less than that of Schedule II and III opioids but similar to opioids in Schedule IV.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA: Both the HHS and DEA state that tramadol is not an immediate precursor of any substance already controlled under the CSA.

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

Proposed Determination of Appropriate Schedule

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

1. Tramadol has a low potential for abuse relative to the drugs or substances in Schedule III. The abuse potential of

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tramadol is comparable to the Schedule IV substance propoxyphene;

2. Tramadol has a currently accepted medical use in treatment in the United States. Tramadol and other tramadol-containing products were approved for marketing by the FDA to manage moderate to moderately severe pain; and

3. Abuse of tramadol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Based on these findings, the Deputy Administrator of the DEA concludes that tramadol [2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol, warrant control in Schedule IV of the CSA (**21 U.S.C. 812**(b)(4)).

Requirements for Handling Tramadol

If this rule is finalized as proposed, persons who handle tramadol would be subject to the CSA's Schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, import, export, research, and conduct of instructional activities, including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research with, or conducts instructional activities with) tramadol, or who desires to handle tramadol would need to be registered with the DEA to conduct such activities, pursuant to **21 U.S.C. 822, 823, 957**, and **958**, and in accordance with **21 CFR parts 1301** and **1312**. Any person who handles tramadol, and is not registered with the DEA, would need to be registered with the DEA to conduct such activities by the effective date of the final rule.

Security. Tramadol would be subject to Schedules III-V security requirements and would need to be handled and stored in accordance with **21 CFR 1301.71-1301.93** pursuant to **21 U.S.C. 821, 823**, and **871**(b).

Labeling and Packaging. All labels and labeling for commercial containers of tramadol distributed on or after finalization of this rule would need to be in accordance with **21 CFR 1302.03-1302.07**, pursuant to **21 U.S.C. 825**, and **958**(e).

Inventory. Every DEA registrant who possesses any quantity of tramadol on the effective date of the final rule would be required to take an inventory of all stocks of tramadol on hand as of the effective date of the rule, pursuant to **21 U.S.C. 827, 958**(e), and in accordance with **21 CFR 1304.03, 1304.04**, and **1304.11**(a) and (d). Any person who becomes registered with the DEA after the effective date of the final rule would be required to take an initial inventory of all stocks of controlled substances (including tramadol) on hand at the time of registration, pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b). After the initial inventory, every DEA registrant would be required to take a biennial inventory of all controlled substances (including tramadol) on hand, pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records. All registrants would be required to maintain records for tramadol or products containing tramadol pursuant to **21 U.S.C. 827, 958**(e), and in accordance with **21 CFR parts 1304** and **1312**, including reports to Automation of Reports and Consolidated Orders System (ARCOS).

Prescriptions. All prescriptions for tramadol or prescriptions for products containing tramadol would be required to be issued pursuant to **21 U.S.C. 829** and in accordance with **21 CFR part 1306**.

Importation and Exportation. All importation and exportation of tramadol would need to be done in accordance with **21 CFR part 1312**, pursuant to **21 U.S.C. 952, 953, 957**, and **958**.

Liability. Any activity with tramadol not authorized by, or in violation of, the CSA, occurring on or after finalization of this proposed rule would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with **21 U.S.C. 811**(a), this proposed 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 (OMB) pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule will 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 proposed rule will not have tribal implications warranting the application of Executive Order 13175. The proposed rule will 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 Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612) (RFA), has reviewed this proposed 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 proposed rule is to place tramadol, including its salts, isomers, salts of isomers, and all isomeric configurations of possible forms, into Schedule IV of the CSA. No less restrictive measures (i.e., non-control or control in Schedule V) would enable the DEA to meet its statutory obligations under the CSA.

This proposed rule affects approximately 1.5 million DEA registrants. If finalized, the proposed rule on the placement of tramadol into Schedule IV of the CSA will affect all persons who handle, or propose to handle, tramadol. Tramadol handlers primarily include: manufacturers, distributors, pharmacies, individual practitioners, mid-level practitioners, and hospital/clinics. For the purpose of this analysis, the DEA assumes all legally operating manufacturers, distributors, importers/exports, pharmacies, individual practitioners, mid-level practitioners, and hospitals/clinics that handle tramadol are registered with the DEA and all distributors, importers/exporters, pharmacies, individual practitioners, mid-level practitioners, and hospital/clinics registered with the DEA are tramadol handlers. While the number of

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DEA registrations forms the basis of the number of businesses affected by this rule, the number of manufacturers affected by this rule is based on industry data. Other than manufacturers, the DEA-estimated "Business-to-Registrant Ratio" is used to estimate the number of businesses represented by DEA registrants, and the "Percent of Business Below SBA Size Standard" is used to determine the number of businesses that are below the Small Business Administration (SBA) size standard (or number of businesses represented by DEA registrants that are small business." The DEA estimates that approximately 367,046 of these to be small entities. When

there are no special considerations for "substantial number" or criteria prescribed by external sources, the DEA uses a general criteria based on percentage. For the purposes of this analysis, a "substantial number" is defined as greater than 30 percent. Therefore, the DEA has determined that this proposed rule will not have an impact on a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this proposed rule on small entities. Specifically, the DEA examined the registration, storage, inventory and recordkeeping, and disposal requirements for the 367,046 small businesses estimated to be affected by the proposed rule. (While approximately 1.5 million DEA registrations are estimated to be affected by this rule, 273,485 registrations are in the 10 states that currently control tramadol as a Schedule IV controlled substance under state law, with requirements that meet or exceed the DEA's requirements for Schedule IV controlled substances. These states include Arkansas, Illinois, Kentucky, Mississippi, New Mexico, New York, North Dakota, Oklahoma, Tennessee, and Wyoming. Therefore, only approximately 1.2 million registrations are estimated to be economically impacted by this rule.) The DEA estimates that 298,354 small businesses total (across all States) would be economically impacted by this rule.

When there are no special considerations for "significant economic impact" or criteria prescribed by external sources, the DEA uses one of two general criteria, revenue -based or profit based. The revenue-based criteria are widely used, while the profit-based criteria can be used for some high-profit industries. For the purposes of this analysis the revenue-based general criteria is used, where if the cost of the rule is greater than one percent of annual revenue, the rule has a "significant" economic impact of the business. To estimate the number of businesses "significantly" impacted by the proposed rule, the DEA first estimated the revenue level associated with the 1 percent criteria for each North American Industry Classification System (NAICS) code associated with the affected entities. Then, using the revenue profile from the 2007 Economic Census, estimated the number of businesses where the cost of the rule is one percent or more than the revenue. This methodology was applied to all NAICS codes, except manufacturers. The estimate of small business manufacturers with significant economic impact is based on publically available data for annual sales data. The DEA estimates that the proposed rule would have a significant economic impact on 573 small businesses (0 manufacturers, 47 distributors/importers/exporters, 74 pharmacies, and 452 practitioners). Based on the DEA's estimate of 376,904 businesses to be affected by the proposed rule, and 367,046 of these estimated to be small businesses, including businesses located in states where tramadol is controlled as Schedule IV under state law, 573 (0.2 percent) of the 367,046 small businesses affected by the proposed rule are estimated to be significantly impacted economically.

The DEA examined the disproportionality of the economic impact. The DEA did not have a basis for differentiating costs for different business sizes, thus one cost estimate was made for each of the registrant business activities. The estimate suggests disproportionality, where smaller (of the small) businesses will bear a larger economic impact as a percentage of revenue. However, the DEA believes that the disproportionality will be mitigated by business volume. A smaller business will handle a lower volume of tramadol, thus requiring less secure storage.

Based on the DEA's understanding of its registrants' operations and facilities, the DEA estimates a non-recurring expense for system modification and initial inventory of $172.24 for all businesses and an additional $10,000 for secure storage for 50 percent of distributors, importers, and exporters. (Fifty percent of distributors, importers, and exporters are estimated to meet the requirements of the proposed rule without the need to expand secure storage area.) The DEA estimates these costs will have significant economic impact on 0 percent of small business manufacturers, 3.3 percent of small business distributors, 0.1 percent of small business pharmacies, and 0.1 percent of practitioners (other than pharmacies), totaling 0.2 percent of all businesses if the proposed rule were finalized. The percentage of small businesses with significant economic impact is below the 30 percent threshold for all registrant categories.

The annual economic effect on the economy is the annual cost per business times the number of affected businesses. The DEA estimated that 306,375 businesses, in States where tramadol is not controlled, were economically affected by the proposed rule. The annual cost of $974.39 is applied to the assumed 50 percent (588) of 1,175 Distributor/Importer/Exporters affected by the proposed rule. Annual cost of $30.46 is applied to remaining businesses affected by the proposed rule: 51 Manufacturer, 587 Distributor/Importer/Exporter, 40,797 Pharmacy, and 264,352 businesses that employ or hold Individual Practitioner, Mid-level Practitioner, and/or Hospital/Clinic registrations. To be conservative in analysis, the higher values for annual costs of $974.39 and $30.46 at 7 percent discount and interest rates is used rather than the annual costs of $698.22 and $26.06 at 3 percent discount and interest rates. The total annual cost is estimated to be $9,887,561.

The DEA's assessment of economic impact by size category indicates that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 et seq.), that this action would not result in any 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, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

- 1. 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.

- 2. Amend **Sec. 1308.14** by adding a new paragraph (b)(3) to read as follows:

Sec. 1308.14 Schedule IV.

* * * * *

(b) * * *

(3) Tramadol [2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers]--9752

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Dated: October 25, 2013.

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2013-25933 Filed 11-1-13; 8:45 am]

BILLING CODE 4410-09-P

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REGISTRATION

Applications, Tools & Resources
CMEA Required Training & Self-Certification
Quota Applications

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Publications & Manuals
Questions & Answers
Significant Guidance Documents
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA

Regulation Committee for Drug Diversion and Responsibility of Pharmacist-in-Charge to Provide Adequate Safeguards

- Met November 25, 2013
- Recommendations to the full Board:
    - For disciplinary matters involving diversion, the name(s) of the pharmacist-in-charge shall be included in the Findings of Fact.
    - Amend Guidance Document 110-27 to add a new section regarding diversion, theft, and loss of controlled substance, to include suggested best practices for safeguarding against diversion of controlled substances.

Virginia Board of Pharmacy
PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

Upon taking over responsibility as PIC:

- You are not a PIC until the Board approves your signed application. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Once you are approved as PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit

within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on 4/30 annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of **all** Schedule ~~II—V~~ II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, on the date you first engage in business as the PIC. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business that day. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy, calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification.

- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -4° and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- ~~Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.~~

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Safeguards against Diversion of All Controlled Substances:

- The PIC "shall provide safeguards against diversion of all controlled substances". This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.
- The PIC shall ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;
- Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm
- Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm
- Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.
- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:
    - Perform state and federal criminal background checks on all personnel with access to controlled substances;
    - Require periodic urine drug screening of all personnel with access to controlled substances;
    - Prohibit personal from bringing smocks or bags into the prescription department;
    - Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;
    - Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;
    - In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconciling all discrepancies;
    - Do not dedicate the management of drug inventory to solely one individual. Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
    - Install surveillance cameras to prevent and/or identify theft or loss of controlled substances;
    - In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

Upon leaving as PIC:

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.

- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense

- Met November 25, 2013
- Recommendations to the full Board:
    - Amend Guidance Document 110-9 as presented in agenda packet
    - Regarding consideration of a suggested penalty for repeat deficiencies – no action recommended at this time
    - Regarding consideration for reduced monetary penalties imposed against free clinic pharmacies – no action recommended at this time
    - Regarding consideration for directing inspectors to provide an expedited pre-hearing consent order to physicians licensed to dispense, following a routine inspection with certain deficiencies – Committee recommended:
        - a process similar to that used for routine pharmacy inspections should be implemented;
        - it reconvene prior to the March 2014 full board meeting to develop a Guidance Document similar to 110-9 to identify deficiencies and suggested monetary penalties;
        - issuing the pre-hearing consent order against the individual physician licensed to dispense. If a common stock of drug is maintained, it is recommended the pre-hearing consent order be issued against the responsible designated practitioner.

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No ~~PIC~~ Pharmacist-in-Charge or ~~PIC~~ Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. ~~PIC~~ Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio First offence – Minor 43 deficiency Second Offense – Major 6 deficiency	100
7. ~~COL~~ Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Major 9a if a drug loss occurred during the period of non-compliance. Minor 44 if no drug loss.	250
10. Unauthorized access to alarm or locking device ~~for Rx~~ to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190	Major 11 if there is evidence that non-compliance contributed to a drug loss. Minor 45 if no drug loss.	500
12. Storage of ~~Rx~~ prescription drugs not in the prescription department	18VAC110-20-190		500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Major 12a if there is evidence that non-compliance contributed to a drug loss. Minor 46 is no drug loss.	250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Minor 13 if only expired drugs not included in inventory.	500
14. No incoming change of ~~PIC~~ Pharmacist-in-Charge inventory ~~taken within 5 days~~, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Cite Minor 13 if only expired drugs not included in inventory.	500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	~~10% threshold~~ Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting final verification of sterile compounding	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Complaint clean room present but not utilized for preparation of compounded sterile drug products.	3000
22. Certification of the direct compounding area (DCA) for ~~CSPs~~ compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level ~~CSPs~~ compounded sterile preparations or high risk ~~CSPs~~ compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000 ~~per incident up to 3 incidents; schedule for IFC for > 3 incidents~~
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level ~~CSPs~~ compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.	5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
25b. High-risk compounded sterile preparations ~~drugs~~ intended for use are improperly stored	54.1-3410.2		5000 ~~per incident up to 3 incidents; schedule for IFC for > 3 incidents~~
25c. Documentation that a person who failed a media-fill test has performed high-risk level ~~CSPs~~ compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		5000 ~~per incident up to 3 incidents; schedule for IFC for > 3 incidents~~
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level ~~CSPs~~ compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated.	500
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations~~CSPs~~ after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. ~~For LTC, ADD being accessed for orders prior to pharmacist review and release~~ Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk ~~CSPs~~ compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Minor 42 – 12/2013. ~~No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports~~	~~18VAC110-20-418~~	~~20% threshold~~	~~0~~
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Minor Deficiencies

If five (5) ~~three (3)~~ or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five~~three~~.

Minor Deficiency	Law/Regulation Cite	Conditions

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Repealed 6/2011		
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Repealed 12/2013~~Decreased hours of operation without public/Board notice~~	~~18VAC110-20-135~~	
4. Sink with ~~No~~ hot~~/~~ and cold running water not available within the prescription department.	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Prescription ~~Rx~~ department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

Minor Deficiency	Law/Regulation Cite	Conditions
11. Storage of prescriptions awaiting delivery outside of the prescription department ~~will call~~ not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, ~~C~~Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
14. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. Minor 17 combined with Minor 16 – 6/2011		
18. ~~CII~~ Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	

Minor Deficiency	Law/Regulation Cite	Conditions
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
25. Compliance packaging or labeling does not ~~conform to USP requirements~~comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
Repackaging, specialty dispensing, compounding:		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
30a. Compounded products not properly labeled	54.1-3410.2	
31. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
32. Personnel preparing compounded sterile preparations ~~performing CSPs~~ do not comply with cleansing and garbing requirements	54.1-3410.2	

Minor Deficiency	Law/Regulation Cite	Conditions
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
Hospital specific or long-term care specific:		
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
35. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
36. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
38. Automated dispensing device ~~ADD~~ loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
39. Emergency medical services ~~EMS~~ procedures or records not in compliance	18VAC110-20-500	10% threshold
40. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
41. Maintaining floor stock in ~~LTCF~~ a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	

Minor Deficiency	Law/Regulation Cite	Conditions
42. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	18VAC110-20-418	20% Threshold. Do not cite deficiency until regulations are approved.
43. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	Per each technician over the ratio First offence – Minor 43 deficiency Second Offense – Major 6 deficiency
44. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Minor 44 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Major 9a if drug loss.
45. Insufficient enclosures or locking devices	18VAC110-20-190	Minor 45 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Major 11 if drug loss.
46. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Minor 46 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Major 12a if drug loss.
47. Particle counts, environmental sampliong, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	

PUBLIC COMMENTS:

The Board received comments from two individuals. Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA), stated that the VPhA had questions regarding Guidance Document 110-36. He requested that the Board reconvene the ad hoc committee for further consideration of the guidance. He then introduced Loyd V. Allen, Jr., Ph.D, R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and *Remington: The Science and Practice of Pharmacy*. Dr. Allen briefly described his experience working as a volunteer member with the U.S. Pharmacopeial (USP) Convention and with the subject of sterile compounding. He prefaced that his comments were his own and not representative of the USP. He provided a handout (Attachment 1) which summarized his concerns with three of the numbered items within Guidance Document 110-36. He stated that USP chapters, such as Chapter <71>, were originally written for manufacturing with later standards written for pharmacy compounding. He is in the process of discerning which chapters he believes apply to manufacturing verses pharmacy compounding; he believes the numbered items referenced in his handout need further clarification. Ms. Allen thanked Mr. Musselman and Dr. Allen for their comments.

DHP DIRECTOR'S REPORT:

Dianne Reynolds-Cane, M.D., Director of the Department of Health Professions (DHP), was unable to attend the meeting due to a scheduling conflict. Arne Owens, Chief Deputy Director, DHP, presented the Director's report on her behalf. Mr. Owens reported that the state plan to reduce prescription drug abuse was submitted to the National Governors Association (NGA) on August 30, 2013. The plan consists of various suggestions and ideas to assist in the reduction of prescription drug abuse. Mr. Owens stated that DHP hosted the NGA Prescription Drug Abuse Policy Reduction meeting on March 25, 2013, and was one of the several state agencies that participated.

A request was made by staff to modify the agenda to include the Regulation Committee recommendation from the meeting that was held on September 9, 2013, regarding 18VAC 110-20-500 concerning emergency medical services (EMS) agencies.

MOTION:

The Board voted unanimously to modify the agenda to include the Regulation Committee recommendation regarding 18VAC 110-20-500 concerning emergency medical services agencies. (motion by Warriner, second by Thornbury)

REGULATIONS:

Ms. Yeatts highlighted certain regulatory activities as included on the update on page 37 of the agenda packet. The request for an extension of the emergency regulations for continuous quality improvement programs (CQI) is currently at the Governor's office. If approved, this will extend the emergency regulations until April 1, 2014. The change to run-dry requirements for automated counting devices was fast-tracked and has been in effect since August 2, 2013. The regulatory reform changes were also fast-tracked, and will become effective on September 26, 2013. The exempt regulatory action for the administration of drugs by emergency

Attachment 1

Virginia Board of Pharmacy
COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Of the 34 items listed, I am in agreement with the majority but have a few comments on the following (The numbers refer to the items phrased as numbered questions). I need to state that this is my personal response as I am acting as an individual and not a representative of the USP. I will provide documentation as appropriate in my responses.

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

Response: The explanation is correct. However, one must keep in mind that most of the USP General Chapters were written for the pharmaceutical manufacturing industry, not for pharmaceutical compounding. Most of the chapters were written prior to the resurgence of pharmaceutical compounding so the terminology relates to manufacturing. However, we are now in the situation where we are trying to apply standards written for large scale manufacturers to small scale compounders. It will take time to get these chapters focused on the correct entities with reasonable standards for each.

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.

Response: Extended BUDs can be used in the absence of direct sterility testing as follows: Note the "program of sterility testing" statement below and the reference from <797> back to <795> regarding BUDs.

<795> PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS
STABILITY CRITERIA AND BEYOND-USE DATING
General Guidelines for Assigning Beyond-Use Dates

"In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for (1) Nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated; and for (2) sterile preparations for which a program of sterility testing is in place."

<797> STORAGE AND BEYOND-USE DATING
Determining Beyond-Use Dates

"...BUDS for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding-Nonsterile Preparations <795>*."

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>?

Response: If high risk batches of 25 or more are compounded, they must pass the sterility test. Batches less than 25 fall in the response to item #4 above.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

Sterility Testing

"All 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 that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs? *The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.

Response: The requirements to meet USP <71> Sterility Tests do not work unless larger quantities of preparation are compounded. For example:

<71> STERILITY TESTS

TEST FOR STERILITY OF THE PRODUCT TO BE EXAMINED

Number of Articles to be Tested

"Unless otherwise specified elsewhere in this chapter or in the individual monograph, test the number of articles specified in Table 3."

Table 3 for Parenteral Preparations includes the following:

Not more than 100 containers.	Test 10% or 4 containers, whichever is the greater.

Comment: In USP <71>, it appears that the minimum number required for testing is 4 containers, unless the volume in each is insufficient for the tests where the number will be increased to 8. If one is compounding less than 4 vials, it does not meet the requirements of this chapter. It is impractical in many cases to prepare additional vials to bring the number up to the minimum required for this chapter. For example, it is not feasible to prepare 5 vials so one can be dispensed and four can be used for sterility testing. One must remember that most of the chapters in the USP General Chapters were designed, developed and written for the pharmaceutical industry, where large volumes are prepared, not for compounding where only a few may be prepared. In addition, many of these CSPs are quite expensive and this prohibits compounding extra units. Also, as mentioned above, I don't know of any hospitals that would compound 5 intravenous admixtures so they could send four for sterility testing and one for the patient. We are in an awkward time when compounding has rapidly grown but many try to apply USP chapters to compounding pharmacy that have been written over the past 30-40 years for the pharmaceutical industry.

Loyd V. Allen, Jr., Ph.D., R.Ph.
Editor-in-Chief
International Journal of Pharmaceutical Compounding
Remington: The Science and Practice of Pharmacy
June 24, 2013

Juran, Caroline (DHP)

From: Rick Schnatz [RXS@usp.org]
Sent: Wednesday, November 20, 2013 2:16 PM
To: Juran, Caroline (DHP)
Subject: Response to Dr. Allen <797> (30)

Hi Caroline,

It was again a pleasure speaking with you last week concerning Dr. Loyd Allen's response to *Compliance with USP Standards for Compounding* issued by your Board of Pharmacy.

As it relates to question #4 I would like to reiterate that USP will be posting an Accelerated Revision on November 22, 2013 as follows:

In accordance with the Rules and Procedures of the 2010-2015 Council of Experts, the Compounding Expert Committee has revised the General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations*. The purpose for the revision is to remove the reference to sterile preparations in the section General Guidelines for Assigning Beyond-Use Dates. The revision will clarify that the beyond-use date (BUD) in the table "BUD by Type of Formulation" is specific for nonsterile preparations and users should refer to General Chapter <797> *Pharmaceutical Compounding—Sterile Preparation* for standards on sterile compounding.

The General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations* Revision Bulletin supersedes the currently official General Chapter. The Revision Bulletin will be incorporated in the Second Supplement to USP 37–NF 32.

Again, the purpose is to be clear to practitioners and regulators that the table titled **BUD by Type of Formulation** in General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations* under the section titled *Stability Criteria and Beyond-Use Dating, General Guidelines for Assigning Beyond-Use Dates* does not apply to compounded sterile preparations (CSPs). As the footnote to the table clearly reads this table only applies to "…nonsterile compounded drug preparations…". Additionally, the following is being removed from the first paragraph of the section titled *General Guidelines for Assigning Beyond-Use Dates* "(2) sterile preparations for which a program of sterility testing is in place (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling*)."

I hope this helps everyone's understanding going forward.

Regards,

Rick

This response has been provided for informational purposes only, and should not be construed as an official interpretation of USP text or relied on to demonstrate compliance with USP standards or requirements.

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⟨795⟩ PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS

INTRODUCTION

The purpose of this chapter is to provide compounders with guidance on applying good compounding practices for the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. This chapter and applicable monographs on formulation help define good compounding practices. Furthermore, this chapter provides general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

DEFINITIONS

ACTIVE PHARMACEUTICAL INGREDIENT (API)—Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

ADDED SUBSTANCES—Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredients, excipients,* and *pharmaceutical ingredients.*

BEYOND-USE DATE (BUD)—The date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

COMPONENT—Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

COMPOUNDER—A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

COMPOUNDING—The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
- Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law

HAZARDOUS DRUG—Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications]

MANUFACTURING—The production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis. Manufacturing may also include any packaging or repackaging of the substance(s) or labeling or relabeling of containers for resale by pharmacies, practitioners, or other persons.

PREPARATION—For the purposes of this chapter, a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms. (For the definitions of *official substance* and *official products,* see *General Notices and Requirements.*)

STABILITY—The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding (see *Stability Considerations in Dispensing Practice* ⟨1191⟩, the table *Criteria for Acceptable Levels of Stability*).

VEHICLE—A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

CATEGORIES OF COMPOUNDING

In the three general categories of nonsterile compounding described in this section, different levels of experience, training, and physical facilities are associated with each category.

Criteria used to determine overall classification include:

- degree of difficulty or complexity of the compounding process
- stability information and warnings
- packaging and storage requirements
- dosage forms
- complexity of calculations
- local versus systemic biological disposition
- level of risk to the compounder
- potential for risk of harm to the patient

See *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩ for risk levels associated with sterile preparations. Specialty areas such as radiopharmaceuticals require special training and are beyond the scope of this chapter. Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound.

Description of Categories

Simple—Making a preparation that has a *United States Pharmacopeia* (*USP*) compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution, Indomethacin Topical Gel,* and *Potassium Bromide Oral Solution, Veterinary.*

Moderate—Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories,* diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.

Complex—Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

RESPONSIBILITIES OF THE COMPOUNDER

The compounder is responsible for compounding preparations of acceptable strength, quality, and purity and in accordance with the prescription or medication order. The compounder is also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, state boards of pharmacy, federal law, and other regulatory agencies where appropriate. Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature. They shall be knowledgeable about the contents of this chapter and should be familiar with *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩, *Pharmaceutical Dosage Forms* ⟨1151⟩, *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩, *Quality Assurance in Pharmaceutical Compounding* ⟨1163⟩, *Prescription Balances and Volumetric Apparatus* ⟨1176⟩, *Stability Considerations in Dispensing Practice* ⟨1191⟩, *Written Prescription Drug Information—Guidelines* ⟨1265⟩, and all applicable compounding laws, guidelines, and standards.

To ensure the quality of compounded preparations, compounders shall adhere to the following general principles (additional information on these general principles is provided in the sections that follow).

General Principles of Compounding

1. Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.
2. Compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *USP* standards.
3. Bulk component containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding.
4. All equipment used in compounding is clean, properly maintained, and used appropriately.
5. The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.
6. Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations.
7. There is assurance that processes are always carried out as intended or specified and are reproducible.
8. Compounding conditions and procedures are adequate for preventing errors.
9. All aspects of compounding are appropriately documented.
10. Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.

COMPOUNDING PROCESS

The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria given in this section (additional information on these criteria is provided in the sections that follow).

Criteria When Compounding Each Drug Preparation

1. The dose, safety, and intended use of the preparation or device has been evaluated for suitability in terms of:
   - the chemical and physical properties of the components
   - dosage form
   - therapeutic appropriateness and route of administration, including local and systemic biological disposition
   - legal limitations, if any
2. A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made. In addition, a Compounding Record should be completed each time a preparation is compounded.
3. Ingredients used in the formulation have their expected identity, quality, and purity. If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov). If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used.
4. Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see the section *Compounding Facilities*).
5. Only one preparation is compounded at one time in a specific workspace.
6. Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used.

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7. A reliable BUD is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.
8. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.
9. The preparation is made in accordance with this chapter, other official standards referenced in this chapter, and relevant scientific data and information.
10. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
11. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record (see chapter ⟨1163⟩).
12. The preparation is packaged as recommended in the *Packaging and Drug Preparation Containers* section of this chapter.
13. The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."
14. The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.
15. The preparation is delivered to the patient or caregiver with the appropriate consultation.

COMPOUNDING FACILITIES

Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩, *Environmental Quality and Control*).

Potable water shall be supplied for hand and equipment washing. This water meets the standards prescribed in the Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141). *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. In those cases when a water is used to prepare a sterile preparation, follow the appropriate monographs and general chapters (see *Water for Pharmaceutical Purposes* ⟨1231⟩).

The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation. Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and an air-drier or single-use towels. The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair. Waste shall be held and disposed of in a sanitary and timely manner and in accordance with local, state, and federal guidelines.

The entire compounding and storage area should be well lighted. Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity*; and the manufacturers' labeled storage conditions). Appropriate temperature and humidity monitoring should be maintained as required for certain components and compounded dosage forms. All components, equipment, and containers shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. The following are references for the safe handling of antineoplastic and hazardous drugs in healthcare settings:

- OSHA Technical Manual—Section VI: Chapter 2, *Controlling Occupational Exposure to Hazardous Drugs*
- NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (DHHS (NIOSH) Publication No. 2004-165) and updates.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

COMPOUNDING EQUIPMENT

The equipment and utensils used for compounding of a drug preparation shall be of appropriate design and capacity. The equipment shall be of suitable composition that the surfaces that contact components are neither reactive, additive, nor sorptive and therefore will not affect or alter the purity of the compounded preparations. The types and sizes of equipment depend on the dosage forms and the quantities compounded (see chapter ⟨1176⟩ and equipment manufacturers' instruction manuals).

Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance, and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned.

Extra care should be used when cleaning equipment used in compounding preparations that require special precaution (e.g., antibiotics and cytotoxic and other hazardous materials). When possible, special equipment should be dedicated for such use, or when the same equipment is being used for all drug products, appropriate procedures shall be in place to allow meticulous cleaning of equipment before use with other drugs. If possible, disposable equipment should be used to reduce chances of bioburden and cross-contamination.

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COMPONENT SELECTION, HANDLING, AND STORAGE

The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations.

1. A *United States Pharmacopeia* (*USP*), *National Formulary* (*NF*), or *Food Chemicals Codex* (*FCC*) substance is the recommended source of ingredients for compounding all preparations.
2. Compounders shall first attempt to use components manufactured in an FDA-registered facility. When components cannot be obtained from an FDA-registered facility, compounders shall use their professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, which should include Certificate of Analysis, manufacturer reputation, and reliability of source.
3. Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided. These preparations may be labeled *USP* or *NF* as appropriate.
4. When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society–certified may be used. However, these components should be used cautiously because the standards for analytical reagents or American Chemical Society–grade materials do not consider whether any impurity present raises human or animal safety concerns.
5. For components in containers that have an expiration date from the manufacturer or distributor, the material may be used in compounding before that expiration date (a) when the material is stored in its original container under conditions to avoid decomposition of the chemicals (see chapter ⟨1191⟩ and *Packaging and Storage Requirements* ⟨659⟩, unless other conditions are noted on the label), (b) when there is minimal exposure of the remaining material each time material is withdrawn from the container, and (c) when any withdrawals from the container are performed by those trained in the proper handling of the material. If the component has been transferred to a different container, that container shall be identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container.
6. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*) based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.
7. If a manufactured drug product is used as the source of active ingredient, the drug product shall be manufactured in an FDA-registered facility, and the manufacturer's product container shall be labeled with a batch control number and expiration date. When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.
8. If the preparation is intended for use as a dietary or nutritional supplement, then the compounder must adhere to this chapter and must also comply with any federal and state requirements. Generally, dietary supplements are prepared from ingredients that meet *USP*, *FCC*, or *NF* standards. Where such standards do not exist, substances may be used in dietary supplements if they have been shown to have acceptable food-grade quality using other suitable procedures.
9. When a component is derived from ruminant animals (e.g., bovine, caprine, ovine), the supplier shall provide written assurance that the component is in compliance with all federal laws governing processing, use, and importation requirements for these materials.
10. When compounding for humans, the compounder should consult the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by FDA (see www.FDA.gov). When compounding for food-producing animals, the compounder should consult the list of components prohibited for use in food-producing animals.
11. All components used in the compounding of preparations must be stored as directed by the manufacturer, or according to *USP*, *NF*, or *FCC* monograph requirements, in a clean area, and under appropriate temperature and humidity conditions (controlled room temperature, refrigerator, or freezer). All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

Change to read:

STABILITY CRITERIA AND BEYOND-USE DATING

The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:

- the nature of the drug and its degradation mechanism
- the dosage form and its components
- the potential for microbial proliferation in the preparation
- the container in which it is packaged
- the expected storage conditions
- the intended duration of therapy (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*).

When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation. Instead, the compounder shall refer to the manufacturer for stability information and

to the literature for applicable information on stability, compatibility, and degradation of ingredients; shall consider stability factors in chapter ⟨1191⟩; and shall use his or her compounding education and experience. All stability data shall be carefully interpreted in relation to the actual compounded formulation.

At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability. For more specific details of some of the common physical signs of deterioration (see chapter ⟨1191⟩, *Observing Products for Evidence of Instability*). However, excessive chemical degradation and other drug concentration loss due to reactions may be invisible more often than visible.

General Guidelines for Assigning Beyond-Use Dates

In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for • (RB 1-Jan-2014) nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated • (RB 1-Jan-2014) (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling*). Drugs or chemicals known to be labile to decomposition will require shorter BUDs.

BUD by Type of Formulation[a]
For 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.
For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

[a] 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.

Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary; to ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential. Antimicrobial preservatives should not be used as a substitute for good compounding practices.

For information on assigning BUDs when repackaging drug products for dispensing or administration, see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date*, and *Packaging and Repackaging—Single-Unit Containers* ⟨1136⟩.

Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs (including ophthalmic preparations) requires strict adherence to guidelines presented in chapter ⟨797⟩ and in the manufacturers' labeling instructions.

PACKAGING AND DRUG PREPARATION CONTAINERS

The compounder shall ensure that the containers and container closures used in packaging compounded preparations meet *USP* requirements (see *Packaging and Storage Requirements* ⟨659⟩; *Containers—Glass* ⟨660⟩; *Containers—Plastics* ⟨661⟩; *Containers—Performance Testing* ⟨671⟩; chapter ⟨1136⟩); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the standards described in them. Container suppliers shall supply, upon request, verification of *USP* container compliance. Containers and container closures intended for the compounding of sterile preparations must be handled as described in chapter ⟨797⟩.

The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded drug preparation. The container used depends on the physical and chemical properties of the compounded preparation. Container–drug interaction should be considered for substances that have sorptive or leaching properties.

The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area.

COMPOUNDING DOCUMENTATION

Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation. All compounders who dispense prescriptions must comply with the record-keeping requirements of their state boards of pharmacy. When the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

These records should be retained for the same period of time that is required for any prescription under state law. The record may be a copy of the prescription in written or machine-readable form and should include a Master Formulation Record and a Compounding Record.

Master Formulation Record

This record shall include:

- official or assigned name, strength, and dosage form of the preparation
- calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- description of all ingredients and their quantities
- compatibility and stability information, including references when available
- equipment needed to prepare the preparation, when appropriate
- mixing instructions that should include:
  1. order of mixing
  2. mixing temperatures or other environmental controls
  3. duration of mixing
  4. other factors pertinent to the replication of the preparation as compounded
- sample labeling information, which shall contain, in addition to legally required information:

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1. generic name and quantity or concentration of each active ingredient
2. assigned BUD
3. storage conditions
4. prescription or control number, whichever is applicable

- container used in dispensing
- packaging and storage requirements
- description of final preparation
- quality control procedures and expected results

Compounding Record

The Compounding Record shall contain:
- official or assigned name, strength, and dosage of the preparation
- Master Formulation Record reference for the preparation
- names and quantities of all components
- sources, lot numbers, and expiration dates of components
- total quantity compounded
- name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation
- date of preparation
- assigned control or prescription number
- assigned BUD
- duplicate label as described in the Master Formulation Record
- description of final preparation
- results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)
- documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver

Standard Operating Procedures

All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel.

Material Safety Data Sheets File

MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises. Employees should be instructed on how to retrieve and interpret needed information.

QUALITY CONTROL

The safety, quality, and performance of compounded preparations depend on correct ingredients and calculations, accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

Compounding Controls

1. The Master Formulation Record, the Compounding Record, and associated written procedures shall be followed in execution of the compounding process. Any deviation in procedures shall be documented.
2. The compounder shall check and recheck each procedure at each stage of the process. If possible, a trained second person should verify each critical step in the compounding process.
3. The compounder shall have established written procedures that describe the tests or examinations conducted on the compounded preparation (e.g., the degree of weight variation among capsules) to ensure their uniformity and integrity.
4. Appropriate control procedures shall be established to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.
5. For further guidance on recommended quality control procedures, see chapter ⟨1163⟩.

PATIENT COUNSELING

At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see *Stability Considerations in Dispensing* ⟨1191⟩, *Responsibility of Pharmacists*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action.

TRAINING

All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training procedure include the following:
- All employees involved in pharmaceutical compounding shall read and become familiar with this chapter. They should also be familiar with the contents of the *USP Pharmacists' Pharmacopeia* and other relevant publications, including how to read and interpret MSDSs.
- All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.
- All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs. For information on training for personnel who compound hazardous drugs, see the references in *Compounding Facilities* earlier in this chapter.
- All training activities shall be documented. The compounder shall meet with employees to review their

work and answer any questions the employees may have concerning compounding procedures.
- The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the direct supervision of, the compounder.
- When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However, the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation.
- When the compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained.
- The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed.
- The compounder is solely responsible for the finished preparation.

COMPOUNDING FOR ANIMAL PATIENTS

A compounder's responsibility for providing patients with high-quality compounded preparations extends beyond the human species. All portions of this chapter apply to compounded preparations formulated for animal patients. Intended use of any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient.

Because humans can consume animal patients as food, care must be taken to prevent drug residues from entering the human food chain when compounded preparations are used in animal patients. For this reason, all compounders preparing formulations for animals shall possess a functional knowledge of drug regulation and disposition in animal patients. Veterinarians are required by law to provide food-producing animal caregivers with an accurate length of time to withhold treated animal tissues (e.g., meat, milk, eggs) from the human food supply. This length of time is referred to as a withdrawal time (WDT) and must also, by law, be included on the dispensing label of every prescription prepared for a food-producing species.

Drug use in any performance animal is strictly regulated by federal and state governments, in addition to the governing bodies of each of the specific disciplines. Penalties for violation of these rules may be severe for all contributing to the violation, including the veterinarian, pharmacist, and caregiver.

The pharmacist shall be knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Extrapolating compounding formulations intended for use in humans may not be appropriate for animal species and may contribute to negative outcomes.

Veterinarians and pharmacists making preparations for animal patients should be familiar with all state and federal regulations regarding drug use in animals, including but not limited to the Food, Drug, and Cosmetic Act; the Animal Drug Amendment; the Animal Medicinal Drug Use Clarification Act; and FDA's Compliance Policy Guideline for Compounding of Drugs for Use in Animal Patients.

District 1 and 2 NABP Meeting in Maine
October 17 – 19, 2013

Meeting was held in Bar Harbor, Maine Thursday thru Saturday. There was good CE and updates from the other states at the roundtable discussion. Joseph Bruno, President of the Maine Board of Pharmacy presided over the meeting and Governor Paul LePage provided some opening remarks.

Dr. Joseph DiPiro was the keynote speaker and discussed the forward progression of the profession challenging the attendees to think outside the box.

District 1 and 2 each held individual business meetings. In our District's meeting we elected Caroline Juran to the Secretary/Treasurer position and Cindy Warriner to the District Chair position. Virginia presented two resolutions in addition the resolution that had been submitted by Pennsylvania prior to the meeting. There was much discussion on the PA resolution and it was amended to reaffirm NABP's existing policy encouraging pharmacies to stop selling tobacco products and work toward a smoke free society. The Virginia resolutions are attached. All resolutions were supported by District 1 also. The resolution addressing educating the public and policy makers to the dangers of obtaining prescription drugs outside of the United States was also expedited unanimously. This means in lieu of waiting until the NABP Annual Meeting in May 2014, the districts approved presenting the resolution directly to the EC for its immediate consideration. Compounding issues, robberies and rogue internet pharmacies were also topics covered at the meeting.

Caroline presented both brochures and a slide show advertising next year's district meeting which will be held in Williamsburg. The presentation was well received and many participants seemed excited to attend.

District 2 Resolution – Permitting Residents to Obtain Drugs from Sources outside the US

Whereas, Maine has enacted a law allowing residents to obtain prescription drugs from sources outside the United States, and

Whereas, these drugs are not FDA-approved drugs and therefore, may not be safe and efficacious, and

Whereas, pharmacies located within the United States must be licensed by their resident Board of Pharmacy and may only dispense FDA-approved drugs, and

Whereas, NABP's research indicates 97 percent of the internet sites do not conform with federal and state laws, often dispensing counterfeit drugs, and

Whereas, there is potential for imminent patient harm with no regulatory oversight from the United States and accountability,

Therefore, be it resolved that NABP continue its efforts in educating state policy makers and the public in the danger of obtaining prescription drugs from sources outside of the United States without federal and state oversight.

District 2 Resolution – Pharmacy Robberies and Thefts

Whereas, in recent years, there has been an increase in armed robberies and internal and external thefts of controlled substances in pharmacies, and

Whereas, armed robberies have resulted in injury and death and continue to pose a significant threat to pharmacy personnel and the public through bodily harm and the illicit use of the stolen controlled substances, and

Whereas, the risk of armed robberies and thefts will potentially continue due to the national epidemic of prescription drug abuse and current economic conditions, and

Whereas, the Boards of Pharmacy are responsible for establishing minimum criteria for the control and safeguards against diversion of drugs and protecting public health and safety,

Therefore, be it resolved that NABP establish a taskforce to review actions taken by member boards to thwart the loss of controlled substances by armed robberies and internal and external thefts of pharmacies and mitigate potential harm to pharmacy personnel and the public, and recommend amendments to the minimum security standards in the Model Act, if necessary.

District 2 Resolution – Pharmacies Selling Tobacco Products

Whereas, In the United States, tobacco use is responsible for nearly 1 in 5 deaths; this equals about 443,000 early deaths each year (Source: *Cancer Facts & Figures 2013*), and

Whereas, state boards of pharmacy are charged with protecting the public health, safety and welfare as related to services provided by pharmacies and pharmacists; and

Whereas, It is an inherent conflict of interest for pharmacies to dispense the medications that treat heart disease, lung disease, and cancer -- and then also sell tobacco, encouraging pharmacies to stop selling tobacco products and work toward a Smoke Free Society

Therefore be it Resolved, that the National Association of Boards of Pharmacy reaffirm its existing policy encouraging pharmacies to stop selling tobacco products and work toward a Smoke Free Society.

Background:

NABP Resolution 88-06-92-

Therefore, Be It Resolved, that NABP encourage the pharmacy community to stop the selling of tobacco products in pharmacies and work toward a Smoke-Free Society by the Year 2000; and Be It Further Resolved, that NABP encourage state boards of pharmacy to support and promote programs that educate the public of the harmful effects of smoking; and Be It Further Resolved, that NABP encourage pharmacists to become non-smoking exemplars to the community in which they live, and that all workplaces of these pharmacists become Smoke-Free by the Year 2000; and Be It Further Resolved, that NABP urge the medical community, related groups, educational institutions, and government agencies, at the federal and state level, to more effectively demonstrate the health hazards in the use of tobacco products and work toward promoting a Smoke-Free Society by the Year 2000.

Virgina Department of Health Professions
Cash Balance
As of October 31, 2013

	107- Pharmacy
Board Cash Balance as of June 30, 2013	$ 2,216,986
YTD FY14 Revenue	168,325
Less: YTD FY14 Direct and In-Direct Expenditures	1,014,429
Board Cash Balance as of October 31, 2013	1,370,882

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2013 through October 31, 2013

	107- Pharmacy			
	Jul '13 - Oct 13	Budget	$ Over Budget	% of Budget
Revenue				
2400 · Fee Revenue				
Administrative Fees	0.00			
2401 · Application Fee	118,445.00	299,010.00	-180,565.00	39.61%
2402 · Examination Fee	0.00			
2406 · License & Renewal Fee	11,725.00	2,352,800.00	-2,341,075.00	0.5%
2407 · Dup. License Certificate Fee	0.00	100.00	-100.00	0.0%
2408 · Board Endorsement - In	0.00			
2409 · Board Endorsement - Out	0.00			
2421 · Monetary Penalty & Late Fees	8,190.00	6,220.00	1,970.00	131.67%
2430 · Board Changes Fee	24,900.00	42,500.00	-17,600.00	58.59%
2432 · Misc. Fee (Bad Check Fee)	35.00	175.00	-140.00	20.0%
Total 2400 · Fee Revenue	163,295.00	2,700,805.00	-2,537,510.00	6.05%
3000 · Sales of Prop. & Commodities				
3007 · Sales of Goods/Svces to State	0.00			
3020 · Misc. Sales-Dishonored Payments	570.00			
Total 3000 · Sales of Prop. & Commodities	570.00			
9000 · Other Revenue				
9060 · Miscellaneous Revenue	3,240.60	750.00	2,490.60	432.08%
9084 · Refund- Prior Yr Disb	1,219.40			
Total 9000 · Other Revenue	4,460.00	750.00	3,710.00	594.67%
Total Revenue	168,325.00	2,701,555.00	-2,533,230.00	6.23%
Expenditures				
1100 · Personal Services				
1110 · Employee Benefits				
1111 · Employer Retirement Contrib.	15,208.20	41,042.00	-25,833.80	37.06%
1112 · Fed Old-Age Ins- Sal St Emp	12,676.79	35,448.00	-22,771.21	35.76%
1113 · Fed Old-Age Ins- Wage Earners	1,043.87	5,642.00	-4,598.13	18.5%
1114 · Group Insurance	2,066.01	5,576.00	-3,509.99	37.05%
1115 · Medical/Hospitalization Ins.	27,642.00	74,952.00	-47,310.00	36.88%
1116 · Retiree Medical/Hospitalizatn	1,736.13	4,686.00	-2,949.87	37.05%
1117 · Long term Disability Ins	815.94	2,202.00	-1,386.06	37.05%
Total 1110 · Employee Benefits	61,188.94	169,548.00	-108,359.06	36.09%
1120 · Salaries				
1123 · Salaries, Classified	169,987.90	468,509.00	-298,521.10	36.28%
1125 · Salaries, Overtime	0.00			
Total 1120 · Salaries	169,987.90	468,509.00	-298,521.10	36.28%
1130 · Special Payments				

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1131 · Bonuses and Incentives	0.00	0.00	0.00	0.0%
1138 · Deferred Compnstn Match Pmts	990.00	3,840.00	-2,850.00	25.78%
Total 1130 · Special Payments	990.00	3,840.00	-2,850.00	25.78%
1140 · Wages				
1141 · Wages, General	14,564.06	73,727.00	-59,162.94	19.75%
Total 1140 · Wages	14,564.06	73,727.00	-59,162.94	19.75%
1150 · Disability Benefits				
1153 · Short-trm Disability Benefits	2,250.08			
Total 1150 · Disability Benefits	2,250.08			
1160 · Terminatn Personal Svce Costs				
1165 · Employee Retirement Contributio	0.00	0.00	0.00	0.0%
Total 1160 · Terminatn Personal Svce Costs	0.00	0.00	0.00	0.0%
Total 1100 · Personal Services	248,980.98	715,624.00	-466,643.02	34.79%
1200 · Contractual Services				
Other Medical Services	0.00			
1210 · Communication Services				
1211 · Express Services	0.00	172.00	-172.00	0.0%
1212 · Outbound Freight Services	0.00			
1214 · Postal Services	7,586.35	34,904.00	-27,317.65	21.74%
1215 · Printing Services	80.00	301.00	-221.00	26.58%
1216 · Telecommunications Svcs (DIT)	2,375.55	7,200.00	-4,824.45	32.99%
1217 · Telecomm. Svcs (Non-State)	0.00			
1219 · Inbound Freight Services	2.87			
Total 1210 · Communication Services	10,044.77	42,577.00	-32,532.23	23.59%
1220 · Employee Development Services				
1221 · Organization Memberships	50.00	805.00	-755.00	6.21%
1222 · Publication Subscriptions	295.00	1,005.00	-710.00	29.35%
1224 · Emp Trning Courses, Wkshp & Cnf	0.00			
1225 · Employee Tuition Reimbursement	0.00			
1227 · Emp Trning- Trns, Ldgng & Meals	0.00			
Total 1220 · Employee Development Services	345.00	1,810.00	-1,465.00	19.06%
1230 · Health Services				
1236 · X-ray and Laboratory Services	0.00	258.00	-258.00	0.0%
Total 1230 · Health Services	0.00	258.00	-258.00	0.0%
1240 · Mgmnt and Informational Svcs				
1242 · Fiscal Services	180.73	36,580.00	-36,399.27	0.49%
1244 · Management Services	68.60	40.00	28.60	171.5%

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	Jul '13 - Oct 13	Budget	$ Over Budget	% of Budget
1246 · Public Infrmtnl & Relation Svcs	75.00	180.00	-105.00	41.67%
1247 · Legal Services	450.00	515.00	-65.00	87.38%
1249 · Recruitment Services	0.00			
Total 1240 · Mgmnt and Informational Svcs	774.33	37,315.00	-36,540.67	2.08%
1250 · Repair and Maintenance Svcs				
1251 · Custodial Services	97.65			
1252 · Electrical Rep & Maintenance	0.00			
1253 · Equip Repair & Maintenance	0.00			
1256 · Mechanical Rep & Maint Svcs	0.00			
1257 · Plant Rep & Maintenance Svcs	0.00	700.00	-700.00	0.0%
Total 1250 · Repair and Maintenance Svcs	97.65	700.00	-602.35	13.95%
1260 · Support Services				
1263 · Clerical Services	10,736.88			
1264 · Food & Dietary Services	518.82	2,453.00	-1,934.18	21.15%
1266 · Manual Labor Services	1,920.75	6,050.00	-4,129.25	31.75%
1267 · Production Services	13,437.73	23,695.00	-10,257.27	56.71%
1268 · Skilled Services	35,854.27	137,954.00	-102,099.73	25.99%
Total 1260 · Support Services	62,468.45	170,152.00	-107,683.55	36.71%
1280 · Transportation Services				
1282 · Travel, Personal Vehicle	4,343.60	4,978.00	-634.40	87.26%
1283 · Travel, Public Carriers	1,010.15			
1284 · Travel, State Vehicles	0.00			
1285 · Travel, Subsistence & Lodging	858.79	2,152.00	-1,293.21	39.91%
1288 · Trvl, Meal Reimb- Not Rprtble	575.00	996.00	-421.00	57.73%
Total 1280 · Transportation Services	6,787.54	8,126.00	-1,338.46	83.53%
Total 1200 · Contractual Services	80,517.74	260,938.00	-180,420.26	30.86%
1300 · Supplies And Materials				
1310 · Administrative Supplies				
1311 · Apparel Supplies	0.00	29.00	-29.00	0.0%
1312 · Office Supplies	359.29	3,574.00	-3,214.71	10.05%
1313 · Stationery and Forms	187.57	1,728.00	-1,540.43	10.86%
Total 1310 · Administrative Supplies	546.86	5,331.00	-4,784.14	10.26%
1320 · Energy Supplies				
1323 · Gasoline	78.86			
Total 1320 · Energy Supplies	78.86			
1330 · Manufctrng and Merch Supplies				
1335 · Packaging and Shipping Suppl	0.00			
Total 1330 · Manufctrng and Merch Supplies	0.00			

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	107- Pharmacy			
	Jul '13 - Oct 13	Budget	$ Over Budget	% of Budget
1340 · Medical and Laboratory Supp.				
1342 · Medical and Dental Supplies	2.64			
1343 · Field Supplies	0.00			
Total 1340 · Medical and Laboratory Supp.	2.64			
1350 · Repair and Maint. Supplies				
1352 · Custodial Rep & Maint Mat'ls	0.00			
1353 · Electrical Repair and Maint	0.00			
Total 1350 · Repair and Maint. Supplies	0.00			
1360 · Residential Supplies				
1362 · Food and Dietary Supplies	81.43	75.00	6.43	108.57%
1363 · Food Service Supplies	17.76	229.00	-211.24	7.76%
1364 · Laundry and Linen Supplies	0.00	8.00	-8.00	0.0%
1365 · Personal Care Supplies	0.00	156.00	-156.00	0.0%
Total 1360 · Residential Supplies	99.19	468.00	-368.81	21.19%
1370 · Specific Use Supplies				
1373 · Computer Operating Supplies	0.00	229.00	-229.00	0.0%
Total 1370 · Specific Use Supplies	0.00	229.00	-229.00	0.0%
Total 1300 · Supplies And Materials	727.55	6,028.00	-5,300.45	12.07%
1400 · Transfer Payments				
1410 · Awards, Contrib., and Claims				
1413 · Premiums	0.00			
1415 · Unemployment Compnsatn Reimb	0.00			
Total 1410 · Awards, Contrib., and Claims	0.00			
Total 1400 · Transfer Payments	0.00			
1500 · Continuous Charges				
S Purch Ch. Card Check Fee	0.00			
1510 · Insurance-Fixed Assets				
1512 · Automobile Liability	0.00			
1516 · Property Insurance	160.74	178.00	-17.26	90.3%
Total 1510 · Insurance-Fixed Assets	160.74	178.00	-17.26	90.3%
1530 · Operating Lease Payments				
1534 · Equipment Rentals	818.59	3,264.00	-2,445.41	25.08%
1535 · Building Rentals	0.00			
1539 · Building Rentals - Non State	17,629.82	51,217.00	-33,587.18	34.42%
Total 1530 · Operating Lease Payments	18,448.41	54,481.00	-36,032.59	33.86%

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	107- Pharmacy			
	Jul '13 - Oct 13	Budget	$ Over Budget	% of Budget
1540 · Service Charges				
1546 · S Purch Ch. Card Check Fee	0.00			
Total 1540 · Service Charges	0.00			
1550 · Insurance-Operations				
1551 · General Liability Insurance	576.95	669.00	-92.05	86.24%
1554 · Surety Bonds	34.04	40.00	-5.96	85.1%
Total 1550 · Insurance-Operations	610.99	709.00	-98.01	86.18%
Total 1500 · Continuous Charges	19,220.14	55,368.00	-36,147.86	34.71%
2200 · Equipment Expenditures				
Electronic & Photo Equip Impr	0.00			
2210 · Computer Equipment				
2218 · Computer Software Purchases	0.00			
Total 2210 · Computer Equipment	0.00			
2220 · Educational & Cultural Equip				
2224 · Reference Equipment	0.00	285.00	-285.00	0.0%
Total 2220 · Educational & Cultural Equip	0.00	285.00	-285.00	0.0%
2230 · Electrnc & Photographic Equip				
2238 · Electronic & Photo Equip Impr	0.00			
Total 2230 · Electrnc & Photographic Equip	0.00			
2260 · Office Equipment				
2261 · Office Appurtenances	0.00			
2262 · Office Furniture	0.00	508.00	-508.00	0.0%
2263 · Office Incidentals	79.54	12.00	67.54	662.83%
2264 · Office Machines	0.00			
2268 · Office Equipment Improvements	0.00	6.00	-6.00	0.0%
Total 2260 · Office Equipment	79.54	526.00	-446.46	15.12%
2270 · Specific Use Equipment				
2271 · Household Equipment	0.00	46.00	-46.00	0.0%
2274 · Non Power Rep & Maint- Equip	19.96			
Total 2270 · Specific Use Equipment	19.96	46.00	-26.04	43.39%
Total 2200 · Equipment Expenditures	99.50	857.00	-757.50	11.61%
Total Direct Expenditures	349,545.91	1,038,815.00	-689,269.09	33.65%
9001 · Allocated Expenditures				
9201 · Behavioral Science Exec	0.00			
9202 · Opt\VM\ASLP Exec Dir	0.00			

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Revenue and Expenditures Summary
July 1, 2013 through October 31, 2013

	107- Pharmacy			
	Jul '13 - Oct 13	Budget	$ Over Budget	% of Budget
9204 · Nursing / Nurse Aid	0.00			
9206 · Funeral\LTCA\PT	0.00			
9301 · DP Operations & Equipment	129,162.78	563,493.36	-434,330.58	22.92%
9302 · Human Resources	19,116.79	47,358.24	-28,241.45	40.37%
9303 · Finance	52,424.15	141,995.64	-89,571.49	36.92%
9304 · Director's Office	24,370.36	83,603.40	-59,233.04	29.15%
9305 · Enforcement	324,235.03	818,124.84	-493,889.81	39.63%
9306 · Administrative Proceedings	31,577.98	109,430.04	-77,852.06	28.86%
9307 · Impaired Practitioners	2,195.83	6,420.24	-4,224.41	34.2%
9308 · Attorney General	50,276.86	65,587.56	-15,310.70	76.66%
9309 · Board of Health Professions	14,842.32	46,740.48	-31,898.16	31.76%
9310 · SRTA	0.00			
9311 · Maintenance and Repairs	10.08	1,307.88	-1,297.80	0.77%
9313 · Emp. Recognition Program	0.00	1,334.03	-1,334.03	0.0%
9314 · Conference Center	114.66	846.96	-732.30	13.54%
9315 · Pgm Devlpmnt & Implmentn	16,556.24	48,697.31	-32,141.07	34.0%
Total 9001 · Allocated Expenditures	664,883.08	1,934,939.98	-1,270,056.90	34.36%
987900 · Cash Trsfr Out- Appr Act Pt. 3	0.00	5,623.43	-5,623.43	0.0%
Total Direct, Allocated and Cash Transfer Expenditures	1,014,428.99	2,979,378.41	-1,964,949.42	34.05%
Net Cash Surplus\Shortfall	**-846,103.99**	**-277,823.41**	**-568,280.58**	**304.55%**