Virginia Regulatory Town Hall

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Exempt Action Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Amends for consistency with Code
Final agency action date	6/7/05
Document preparation date	6/7/05

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 21 (02) and 58 (99).

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Chapter 200 of the 2005 Acts of the Assembly amended § 54.1-3410.2 relating to requirements for compounding drugs. Since some provisions of Chapter 20 of the Board of Pharmacy, especially Part X on Compounding Sterile Pharmaceutical Products are in conflict with the amended Code and others are now redundant, the Board has determined that regulations must be amended for consistency with the Code of Virginia.

> § 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.
>
> A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ~~maintain and comply with a policy and procedure manual when engaging in the levels of compounding of drug products associated with any of the following: (i) higher risk from contamination in compounding, such as the compounding of sterile injectable products, sterile ophthalmic or otic products, total parenteral nutrition products, chemotherapy injectable products and implants; (ii) radiopharmaceuticals; or (iii) preparation of dosage forms that are dose-critical or are specialized preparations, such as slow-release products or transdermal patches~~ *ensure compliance with USP-NF standards for both sterile and non-sterile compounding*.

~~Such manual shall (i) be consistent with USP-NF standards and guidance for compounding; (ii) describe all significant procedures in compounding; and (iii) establish a quality assurance program to ensure accountability, accuracy, quality, safety, and uniformity.~~

~~A policy and procedure manual shall not be required for nonsterile compounding that only involves the mixing of two or more commercially available preparations, the mixing or~~

~~reconstitution of a commercially available product in accordance with the manufacturer's instructions, preparation of injections for immediate administration using commercially available sterile products, preparation of other nonsterile dosage forms that are not dose-critical or specialized products, and the addition of flavoring.~~

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal; or

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, or (iii) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, ~~All compounding~~ records *for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used* shall include: ~~(i) the date of the preparation; (ii)~~ the generic name and the name of the

manufacturer of ~~the raw materials~~ *each component* or the brand name of ~~the raw materials~~ *each component*; ~~(iii)~~ the manufacturer's lot number and expiration date for each component~~, and,~~ *or* when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; ~~(iv) the prescription number or~~ the assigned lot number ~~when compounding in anticipation of receiving a prescription; (v) the signature or initials of the pharmacist or other authorized person performing the compounding; (vi) the signature or initials of the pharmacist responsible for supervising support personnel and conducting in-process and final checks of compounded products when other authorized personnel perform the compounding function; (vii) the quantity in units of finished products or quantity of raw materials used in compounding the product; (viii)~~ *if subdivided,* the *unit or* package size and the number of units *or packages* prepared; *and* ~~(ix)~~ the beyond-use date ~~and the criteria used for determining this date;~~. *The criteria for establishing the beyond-use date shall be available for inspection by the Board.* ~~(x) for the levels of compounding described in subsection E, requiring the maintenance and compliance with a policy and procedure manual, a complete formula with compounding procedures, including, when appropriate, complete mixing instructions with the order of mixing, mixing temperatures or other environmental controls, duration of mixing, equipment needed, and other factors necessary to replicate the preparation as compounded; and (xi) documentation for the levels of compounding described in subsection E of any tests conducted on compounded products in accordance with the required policy and procedure manual.~~

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304 and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 7, 2005, the Board of Pharmacy adopted an exempt action to eliminate certain definitions that are no longer necessary in Section 10, repeal Part X (Sections 411 through 416) on Sterile Compounding and add Section 321 to require compliance with national standards (USP-NF) and the Code of Virginia (§ 54.1-3410.2) when compounding a drug product. Although required to comply with the Virginia Register Act, the agency is exempt from provisions of the Administrative Process Act for the implementation of these regulations pursuant to § 2.2-

4006 A 4, which grants an exemption if the action is: "Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved."

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

There is no impact of this regulatory action on the institution of the family and family stability.