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HOUSE BILL NO. 917

Offered January 14, 2026

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A BILL to amend and reenact §§ 54.1-3406 and 54.1-3410.2 of the Code of Virginia, relating to Board of Pharmacy; compounding pharmacies; use of bulk drug substances; recordkeeping.

Patrons—Willett and Guzman

Committee Referral Pending

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3406 and 54.1-3410.2 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with § 54.1-3410.2.

C. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the National Association of Boards of Pharmacy any reports, information, or records received and maintained by the Board in connection with disciplinary proceedings or inspections of a licensee.

§ 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, except for distribution within health systems under common ownership when the compounded drug products are administered only to patients within the hospital or health system; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

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 provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law

or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians 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; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the 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 ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

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; or are manufactured by an establishment that is registered by the FDA~~ *or are drug substances that appear on the list developed by the FDA pursuant to 21 U.S.C. 353a(b)(1)(A)(i)(III)*; and

2. *Comply with the following requirements:*

a. The bulk drug substance is a pharmaceutical grade product, as stated in the certificate of analysis or other materials describing the substance;

b. The bulk drug substance is accompanied by a valid certificate of analysis containing all information material to the safety and effectiveness of the drug compounded using the bulk drug substance, including the identity and content of the bulk drug substance, the country where the bulk drug substance was originally manufactured, the identity of any impurity including the chemical name and amount present, and any additional element that the Board may by regulation require;

c. The pharmacist obtains proof that the manufacture of the bulk drug substance took place in an establishment that:

(1) Is duly registered with the FDA under § 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360); and

(2) Has undergone an inspection by the FDA as a human drug establishment within the last two years and such inspection (i) included current good manufacturing practice compliance and covered the relevant bulk drug substance and (ii) was classified as "voluntary action indicated" or "no action indicated";

d. The pharmacist conducts and documents quality control testing or obtains documentation of such testing of the bulk drug substance prior to its use in a compounded drug to confirm:

(1) The identity and content of the bulk drug substance; and

(2) That impurities present are identified, characterized, quantified, and justified given the product and its intended use; and

e. The bulk drug substance otherwise complies with the Federal Food, Drug, and Cosmetic Act; and

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and 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~~ *contains a bulk drug substance that (i) the FDA has placed on the list of drug products* 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~~ *for reasons of safety or effectiveness set forth in 21 C.F.R. § 216.24 or any successor FDA regulation or (ii) that is covered or was ever covered by an effective investigational new drug application under 21 U.S.C. § 355(i) and has not been approved by the*

FDA;

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, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product~~

a. A compounded drug product is essentially a copy of a commercially available drug product if it is a preparation that includes or claims to include any bulk drug substance that is found in a commercially available drug product, unless (i) the compounded drug makes a change for an identified individual patient, which produces for that patient a clinically significant difference, as determined by the prescribing practitioner and verified by the compounding pharmacist, or (ii) the prescriber has indicated in the oral or written prescription for an individual that there is an emergent need for a drug to treat a serious or life-threatening condition that is not readily available within the time medically necessary. The combination of multiple active ingredients that could be administered separately does not constitute a clinically significant difference.

b. Documentation of a prescriber's determination of a clinically significant difference must include (i) the medical reason, other than cost or convenience, why a commercially available drug product cannot be used and (ii) how the compounded product is different from the commercially available drug product such that it produces a clinically significant therapeutic response in the patient that addresses the medical reason why the patient could not use a commercially available drug product. A prepopulated or prefilled prescription form or order, an electronic equivalent thereof, or any form of automated notation shall not be considered adequate documentation of a prescriber's determination of a clinically significant difference for a compounded drug. The Board may further define the documentation necessary to document a prescriber's determination of a clinically significant difference by regulation.

c. For the purposes of this subdivision H 2, "commercially available drug product" means a drug product that has been approved by the FDA and is not included in the discontinued section of the list described in 21 U.S.C. § 355(j)(7)(A); or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

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. *The Board may request a pharmacist provide the records it maintains pursuant to this subsection. The pharmacist shall make available for inspection or audit such records within 48 hours of a request by the Board or an authorized agent or within a reasonable time as determined by the Board based on the circumstances of the request.*

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, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; ~~and~~ the beyond-use date*; and quality control testing by the pharmacy*. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

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.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

2. That the Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall provide an opportunity for public comment on the regulations prior to adoption.