2015 SESSION

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HOUSE BILL NO. 1119

Offered January 13, 2014

3 A BILL to amend and reenact § 54.1-3410.2 of the Code of Virginia, relating to compounding of drug 4 products; notice. 5

> Patron-Habeeb Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3410.2 of the Code of Virginia is amended and reenacted as follows: 10

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; 11 labeling and record maintenance requirements. 12

13 A. A pharmacist may engage in compounding of drug products when the dispensing of such 14 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. 15

16 Pharmacists shall (i) notify the patient to whom a compounded drug product is dispensed of the fact that the drug product has been compounded, (ii) label all compounded drug products that are dispensed 17 pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall (iii) 18 19 include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance 20 with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of 21 prescriptions based on a routine, regularly observed prescribing pattern. 22

23 Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of 24 the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned 25 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 26 27 (iv) the quantity.

28 C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not 29 distribute compounded drug products for subsequent distribution or sale to other persons or to 30 commercial entities, including distribution to pharmacies or other entities under common ownership or 31 control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions 32 33 to alternate delivery locations pursuant to \$ 54.1-3420.2.

34 A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, 35 podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their 36 professional practice, either personally or under their direct and immediate supervision.

37 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 38 39 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 40 41 compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which 42 43 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 44 procedures, and appearance of the final product. 45

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile 46 47 compounding. 48

 \hat{F} . Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

49 1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary 50 monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy 51 compounding; or are drug substances that are components of drugs approved by the FDA for use in the 52 United States; or are otherwise approved by the FDA; 53

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

54 3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, 55 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 56 reputation, or reliability of the source. 57

G. Pharmacists may compound using ingredients that are not considered drug products in accordance 58

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59 with the USP-NF standards and guidance on pharmacy compounding. 60

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 61 62 market by the FDA because such drug product or a component of such drug product has been found to 63 be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

64 2. The regular compounding or the compounding of inordinate amounts of any drug products that are 65 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 66 ordered by the prescriber for an individual patient, (ii) the compounding of a commercially 67 manufactured drug only during times when the product is not available from the manufacturer or 68 supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified 69 70 the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a 71 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 72 73 time medically necessary, or (v) the mixing of two or more commercially available products regardless 74 of whether the end product is a commercially available product; or

75 3. The compounding of inordinate amounts of any preparation in cases in which there is no observed 76 historical pattern of prescriptions and dispensing to support an expectation of receiving a valid 77 prescription for the preparation. The compounding of an inordinate amount of a preparation in such 78 cases shall constitute manufacturing of drugs.

79 I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, 80 formula record, formula book, or other log or record. Records may be maintained electronically, 81 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 82 83 pursuant to a prescription order for a single patient where only manufacturers' finished products are used 84 as components shall include the name and quantity of all components, the date of compounding and 85 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 86 compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy 87 88 technician and verifying the accuracy and integrity of compounded products.

89 2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or 90 batch in advance of dispensing or when bulk drug substances are used shall include: the generic name 91 and the name of the manufacturer of each component or the brand name of each component; the 92 manufacturer's lot number and expiration date for each component or when the original manufacturer's 93 lot number and expiration date are unknown, the source of acquisition of the component; the assigned 94 lot number if subdivided, the unit or package size and the number of units or packages prepared; and 95 the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection 96 by the Board.

97 3. A complete compounding formula listing all procedures, necessary equipment, necessary 98 environmental considerations, and other factors in detail shall be maintained where such instructions are 99 necessary to replicate a compounded product or where the compounding is difficult or complex and 100 must be done by a certain process in order to ensure the integrity of the finished product.

101 4. A formal written quality assurance plan shall be maintained that describes specific monitoring and 102 evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained 103 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 104 environmental controls and equipment calibration, and any end-product testing, if applicable. 105

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 106 107 108 section and the relevant Board regulations.

109 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 110 otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its 111 permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to 112 113 continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. 114 Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et 115 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. 116