

SENATE BILL NO. 1366
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on January 30, 2025)
(Patron Prior to Substitute—Senator Pillion)

A BILL to amend and reenact § 54.1-3410.2 of the Code of Virginia, relating to compounding drugs; exceptions for distribution within hospital or health system.

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:

§ 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

60 compounding.

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

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

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

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

73 H. Pharmacists shall not engage in the following:

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 The compounding for human use of a drug product that has been withdrawn or removed from the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

77 2. The regular compounding or the compounding of inordinate amounts of any drug products that are
78 essentially copies of commercially available drug products. However, this prohibition shall not include (i) the
79 compounding of any commercially available product when there is a change in the product ordered by the
80 prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during
81 times when the product is not available from the manufacturer or supplier, (iii) the compounding of a
82 commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due
83 to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber
84 has indicated in the oral or written prescription for an individual patient that there is an emergent need for a
85 drug that is not readily available within the time medically necessary, or (v) the mixing of two or more
86 commercially available products regardless of whether the end product is a commercially available product;
87 or

88 3. The compounding of inordinate amounts of any preparation in cases in which there is no observed

89 historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription
90 for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute
91 manufacturing of drugs.

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

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

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

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

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

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

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