

## 1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 *An Act to amend and reenact § 54.1-3457 of the Code of Virginia and to amend the Code of Virginia by*  
 3 *adding a section numbered 54.1-3408.06, relating to therapeutic interchange and adaptation.*

4 [S 418]

5 Approved

6 **Be it enacted by the General Assembly of Virginia:**7 **1. That § 54.1-3457 of the Code of Virginia is amended and reenacted and that the Code of Virginia is**  
 8 **amended by adding a section numbered 54.1-3408.06 as follows:**9 **§ 54.1-3408.06. Therapeutic interchange and adaptation.**10 *A. A pharmacist may perform a therapeutic interchange by substituting a drug with another drug in the*  
 11 *same therapeutic class that the pharmacist believes will have a similar therapeutic effect and adverse-*  
 12 *reaction profile when administered in a therapeutically equivalent dose as the prescribed drug, provided that*  
 13 *the substitution lowers the cost or is cost-neutral to the patient or occurs during a drug shortage, and the*  
 14 *substitution is made in accordance with Board regulations.*15 *For purposes of this section, a drug shall be deemed to be in a drug shortage when such drug appears on*  
 16 *either the (i) U.S. Food and Drug Administration drug shortage list or (ii) American Society of Health System*  
 17 *Pharmacists drug shortage list.*18 *B. A pharmacist may adapt a prescription drug order by:*19 *1. Changing the drug name, strength, directions, or quantity of medication prescribed when performing a*  
 20 *therapeutic interchange in accordance with Board regulations;*21 *2. Changing the dosage form of a prescription if it is in the best interest of patient care, so long as the*  
 22 *prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed;*23 *3. Changing the quantity of medication prescribed if the prescribed quantity or package size is not*  
 24 *commercially available or the change in quantity is related to a change in dosage form as authorized by this*  
 25 *subsection; or*26 *4. Completing missing information on a prescription if there is evidence to support the change.*27 *C. If a pharmacist performs a therapeutic interchange, the pharmacist shall notify the prescriber within*  
 28 *24 hours of such change being made.*29 *D. Nothing in this section shall be construed to prevent a prescriber from indicating that substitutions for*  
 30 *the prescribed drug are not appropriate by checking the "Dispense as Written" box.*31 **§ 54.1-3457. Prohibited acts.**

32 The following acts shall be prohibited:

33 *1. The manufacture, sale, delivery, holding, or offering for sale of any drug, device, or cosmetic that is*  
 34 *adulterated or misbranded.*35 *2. The adulteration or misbranding of any drug, device, or cosmetic.*36 *3. The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and the*  
 37 *delivery or proffered delivery thereof for pay or otherwise.*38 *4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of*  
 39 *§ 54.1-3421.*40 *5. The dissemination of any false advertisement.*41 *6. The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or*  
 42 *copying of any record.*43 *7. The giving of a false guaranty or undertaking.*44 *8. The removal or disposal of a detained article in violation of § 54.1-3459.*45 *9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling*  
 46 *of, or the doing of any other act with respect to, a drug, device, or cosmetic, if such act is done while such*  
 47 *article is held for sale and results in such article being adulterated or misbranded.*48 *10. The forging, counterfeiting, simulating, or falsely representing, or without proper authority using of*  
 49 *any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated*  
 50 *under the provisions of this chapter or of the federal act.*51 *11. The using by any person to his own advantage, or revealing, other than to the Board or its authorized*  
 52 *representative or to the courts when relevant in any judicial proceeding under this chapter of any information*  
 53 *acquired under authority of this chapter concerning any method or process which as a trade secret is entitled*  
 54 *to protection.*55 *12. The using, on the labeling of any drug or in any advertisement relating to such drug, of any*  
 56 *representation or suggestion that an application with respect to such drug is effective under § 54.1-3421, or*

57 that such drug complies with the provisions of such section.

58 13. In the case of a drug distributed or offered for sale in this Commonwealth, the failure of the  
59 manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner  
60 licensed by applicable law to administer such drug who makes written request for information as to such  
61 drug, true and correct copies of all printed matter which is required to be included in any package in which  
62 that drug is distributed or sold, or such other printed matter as is approved under the federal act. This  
63 subdivision shall not be construed to exempt any person from any labeling requirement imposed by or under  
64 other provisions of this chapter.

65 14. Placing or causing to be placed upon any drug or device or container, with intent to defraud, the trade  
66 name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or selling,  
67 dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in  
68 possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container  
69 thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of  
70 any of the foregoing has been placed thereon in a manner prohibited by this section or making, selling,  
71 disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or  
72 concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark,  
73 trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing  
74 upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

75 15. The doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the  
76 holding for sale or dispensing, of a counterfeit drug.

77 16. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand  
78 of drug ordered or prescribed without the permission of the person ordering or prescribing, except as  
79 provided in § 54.1-3408.03 relating to dispensing of therapeutically equivalent drugs *and* § 54.1-3408.06  
80 *relating to therapeutic interchange and adaptation.*

81 17. Dispensing or causing to be dispensed a biosimilar in place of a prescribed biological product or brand  
82 of biological product, except as provided in § 54.1-3408.04 related to dispensing of interchangeable  
83 biosimilars *and* § 54.1-3408.06 *related to therapeutic interchange and adaptation.*

84 **2. That the Board of Pharmacy shall promulgate regulations in accordance with this act, which shall**  
85 **include determination of which therapeutic classes of drugs are eligible for therapeutic interchange**  
86 **and which therapeutic classes shall be prohibited.**