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HOUSE BILL NO. 2312

Offered January 18, 2013

A BILL to amend and reenact §§ 54.1-2408.1, 54.1-3401, 54.1-3410.2, 54.1-3434.1, and 54.1-3434.2 of the Code of Virginia, relating to compounding pharmacies.

Patron—Jones

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2408.1, 54.1-3401, 54.1-3410.2, 54.1-3434.1, and 54.1-3434.2 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2408.1. Summary action against licenses, certificates, registrations, or multistate licensure privilege; allegations to be in writing.

A. Any health regulatory board may suspend the license, certificate, registration, *permit*, or multistate licensure privilege of any person holding a license, certificate, registration, *permit*, or licensure privilege issued by it without a hearing simultaneously with the institution of proceedings for a hearing, if the relevant board finds that there is a substantial danger to the public health or safety which warrants this action. A board may meet by telephone conference call when summarily suspending a license, certificate, registration, *permit*, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension.

B. Any health regulatory board may restrict the license, certificate, registration, *permit*, or multistate licensure privilege of any person holding a license, certificate, registration, *permit*, or licensure privilege issued by it without proceeding simultaneously with notification of an informal conference pursuant to §§ 2.2-4019 and 54.1-2400, if the relevant board finds that there is a substantial danger to the public health or safety that warrants this action. A board may meet by telephone conference call when summarily restricting a license, certificate, registration, *permit*, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. The informal conference shall be scheduled within a reasonable time of the date of the summary restriction.

C. Allegations of violations of this title shall be made in writing to the relevant health regulatory board.

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that

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59 are used in the synthesis of such substances.

60 "Change of ownership" of an existing entity permitted, registered or licensed by the Board means (i)
61 the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns
62 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a
63 partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more
64 of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation
65 of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the
66 voting stock of which is actively traded on any securities exchange or in any over-the-counter market;
67 (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned
68 subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a
69 corporation's charter.

70 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a
71 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
72 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
73 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
74 expectation of receiving a valid prescription based on observed *historical patterns of prescribing patterns*
75 *and dispensing*; (ii) by ~~or for~~ a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary
76 medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled
77 substance in the course of his professional practice; or (iii) for the purpose of, or as incident to,
78 research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or
79 reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when
80 performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a
81 person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person
82 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to
83 subdivision A 4 of § 54.1-2901 shall not be considered compounding.

84 "Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of
85 this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms
86 are defined or used in Title 3.2 or Title 4.1.

87 "DEA" means the Drug Enforcement Administration, United States Department of Justice, or its
88 successor agency.

89 "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by
90 this chapter, whether or not there exists an agency relationship.

91 "Device" means instruments, apparatus, and contrivances, including their components, parts and
92 accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in
93 man or animals or to affect the structure or any function of the body of man or animals.

94 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
95 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§
96 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician
97 assistant or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a
98 Medicare-certified renal dialysis facility.

99 "Dialysis solution" means either the commercially available, unopened, sterile solutions whose
100 purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal
101 dialysis, or commercially available solutions whose purpose is to be used in the performance of
102 hemodialysis not to include any solutions administered to the patient intravenously.

103 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the
104 lawful order of a practitioner, including the prescribing and administering, packaging, labeling or
105 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include
106 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites
107 operated by such practitioner or that practitioner's medical practice for the purpose of administration of
108 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For
109 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a
110 practitioner to patients to take with them away from the practitioner's place of practice.

111 "Dispenser" means a practitioner who dispenses.

112 "Distribute" means to deliver other than by administering or dispensing a controlled substance.

113 "Distributor" means a person who distributes.

114 "Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia
115 National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to
116 any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or
117 prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect
118 the structure or any function of the body of man or animals; or (iv) articles or substances intended for
119 use as a component of any article specified in clause (i), (ii) or (iii). "Drug" does not include devices or
120 their components, parts or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order, which is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the United States Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Label" means a display of written, printed or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus *Cannabis* whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, unless such stalks, fiber, oil or cake is combined with other parts of plants of the genus *Cannabis*.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means: (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such

182 conditions.

183 "Nuclear medicine technologist" means an individual who holds a current certification with the
184 American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification
185 Board.

186 "Official compendium" means the official United States Pharmacopoeia National Formulary, official
187 Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

188 "Official written order" means an order written on a form provided for that purpose by the United
189 States Drug Enforcement Administration, under any laws of the United States making provision therefor,
190 if such order forms are authorized and required by federal law, and if no such order form is provided
191 then on an official form provided for that purpose by the Board of Pharmacy.

192 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to
193 morphine or being capable of conversion into a drug having such addiction-forming or
194 addiction-sustaining liability. It does not include, unless specifically designated as controlled under
195 Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts
196 (dextromethorphan). It does include its racemic and levorotatory forms.

197 "Opium poppy" means the plant of the species *Papaver somniferum* L., except the seeds thereof.

198 "Original package" means the unbroken container or wrapping in which any drug or medicine is
199 enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor
200 for use in the delivery or display of such article.

201 "Person" means both the plural and singular, as the case demands, and includes an individual,
202 partnership, corporation, association, governmental agency, trust, or other institution or entity.

203 "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application
204 for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in
205 a manner complying with the laws and regulations for the practice of pharmacy and the sale and
206 dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy
207 and the pharmacy's personnel as required by § 54.1-3432.

208 "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

209 "Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01,
210 licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified
211 optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator,
212 or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and
213 administer, or conduct research with respect to, a controlled substance in the course of professional
214 practice or research in the Commonwealth.

215 "Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue
216 a prescription.

217 "Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word
218 of mouth, telephone, telegraph or other means of communication to a pharmacist by a duly licensed
219 physician, dentist, veterinarian or other practitioner, authorized by law to prescribe and administer such
220 drugs or medical supplies.

221 "Prescription drug" means any drug required by federal law or regulation to be dispensed only
222 pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of
223 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353 (b)).

224 "Production" or "produce" includes the manufacture, planting, cultivation, growing or harvesting of a
225 controlled substance or marijuana.

226 "Proprietary medicine" means a completely compounded nonprescription drug in its unbroken,
227 original package which does not contain any controlled substance or marijuana as defined in this chapter
228 and is not in itself poisonous, and which is sold, offered, promoted or advertised directly to the general
229 public by or under the authority of the manufacturer or primary distributor, under a trademark, trade
230 name or other trade symbol privately owned, and the labeling of which conforms to the requirements of
231 this chapter and applicable federal law. However, this definition shall not include a drug which is only
232 advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic,
233 a drug which may be dispensed only upon prescription or the label of which bears substantially the
234 statement "Warning - may be habit-forming," or a drug intended for injection.

235 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei
236 with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or
237 radionuclide generator that is intended to be used in the preparation of any such substance, but does not
238 include drugs such as carbon-containing compounds or potassium-containing salts that include trace
239 quantities of naturally occurring radionuclides. The term also includes any biological product that is
240 labeled with a radionuclide or intended solely to be labeled with a radionuclide.

241 "Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any
242 person, whether as an individual, proprietor, agent, servant or employee.

243 "Therapeutically equivalent drug products" means drug products that contain the same active

ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 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 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

305 compounding; or are drug substances that are components of drugs approved by the FDA for use in the
306 United States; or are otherwise approved by the FDA;

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

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

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

314 H. Pharmacists shall not engage in the following:

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

318 2. The regular compounding or the compounding of inordinate amounts of any drug products that are
319 essentially copies of commercially available drug products. However, this prohibition shall not include
320 (i) the compounding of any commercially available product when there is a change in the product
321 ordered by the prescriber for an individual patient, (ii) the compounding of a commercially
322 manufactured drug only during times when the product is not available from the manufacturer or
323 supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified
324 the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a
325 commercially manufactured drug when the prescriber has indicated in the oral or written prescription for
326 an individual patient that there is an emergent need for a drug that is not readily available within the
327 time medically necessary, or (v) the mixing of two or more commercially available products regardless
328 of whether the end product is a commercially available product; or

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

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

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

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

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

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

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

363 **§ 54.1-3434.1. Nonresident pharmacies to register with Board.**

364 A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner,
365 Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be
366 considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in

charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering *or renewing a registration* with the Board, the nonresident pharmacy shall submit a copy of ~~the most recent~~ *a current* inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located *that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding*. The inspection report shall be deemed current *for the purpose of this subdivision* if the inspection was conducted ~~within the past five years~~ *(i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board*. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the ~~past five years~~ *required period*, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

§ 54.1-3434.2. Permit to be issued.

The Board shall only register nonresident pharmacies that maintain a current unrestricted license,

428 certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within
429 another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers
430 within the United States.

431 Applications for a nonresident pharmacy registration, under this section, shall be made on a form
432 furnished by the Board. The Board may require such information as it deems is necessary to carry out
433 the purpose of the section.

434 The permit or nonresident pharmacy registration shall be renewed annually on a date determined by
435 the Board in regulation. Renewal is contingent upon the nonresident pharmacy providing documentation
436 of *a current inspection report in accordance with subdivision A 3 of § 54.1-3434.1*; continuing current,
437 unrestricted licensure in the resident jurisdiction; and continuing certification if required in subdivision
438 A 4 of § 54.1-3434.1.