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## **SENATE BILL NO. 1363**

Offered January 13, 2025

Prefiled January 13, 2025

# A BILL to amend and reenact §§ 54.1-109, 54.1-113, 54.1-2400, 54.1-2409, 54.1-2410, 54.1-2411, 54.1-2412, 54.1-2500, 54.1-2503, 54.1-2505, 54.1-2506, 54.1-2729.2, 54.1-2729.3, 54.1-2731, 54.1-3401, and 54.1-3408 of the Code of Virginia and to repeal §§ 54.1-2409.2 and 54.1-2507 through 54.1-2510 of the Code of Virginia, relating to elimination of Board of Health Professions; transfer of powers and duties.

Patron—Pillion

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-109, 54.1-113, 54.1-2400, 54.1-2409, 54.1-2410, 54.1-2411, 54.1-2412, 54.1-2500, 54.1-2503, 54.1-2505, 54.1-2506, 54.1-2729.2, 54.1-2729.3, 54.1-2731, 54.1-3401, and 54.1-3408 of the

Code of Virginia are amended and reenacted as follows:

# § 54.1-109. Reviews and appeals.

Any person who has been aggrieved by any action of the Department of Professional and Occupational 17 18 Regulation, the Department of Health Professions, the Board for Professional and Occupational Regulation, 19 Board of Health Professions, any regulatory board within the Departments, or any panel of a health 20 regulatory board convened pursuant to § 54.1-2400 shall be entitled to a review of such action. Appeals from 21 such actions shall be in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et 22 seq.). 23

## § 54.1-113. Regulatory boards to adjust fees; certain transfer of moneys collected on behalf of health regulatory boards prohibited.

A. Following the close of any biennium, when the account for any regulatory board within the Department of Professional and Occupational Regulation maintained under § 54.1-308 shows that unspent and unencumbered revenue exceeds \$100,000 or 20 percent of the total expenses allocated to the regulatory board for the past biennium, whichever is greater, the regulatory board shall (i) distribute all such excess revenue to current regulants and (ii) reduce the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

B. Following the close of any biennium, when the account for any regulatory board within the Department of Health Professions maintained under § 54.1-2505 shows expenses allocated to it for the past biennium to be more than 10 percent greater or less than moneys collected on behalf of the regulatory board, it shall revise the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

C. Nongeneral funds generated by fees collected on behalf of the health regulatory boards and accounted for and deposited into a special fund by the Director of the Department of Health Professions shall be held exclusively to cover the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department and Board of Health Professions and shall not be transferred to any agency other than the Department of Health Professions, except as provided in §§ 54.1-3011.1 and 54.1-3011.2.

## § 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law which that are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.

53 5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all 54 expenses for the administration and operation of the Department of Health Professions, the Board of Health 56 Professions, and the health regulatory boards.

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions

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59 for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or 60 issued a multistate licensure privilege by a health regulatory board through delivery of health care services,

without compensation, to low-income individuals receiving health services through a local health department 61

62 or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations

shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 63 25 (§ 54.1-2500 et seq.).

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65 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license, permit, or multistate licensure privilege which that such board has authority to issue for causes enumerated in applicable 66 law and regulations.

68 8. To appoint designees from their membership or immediate staff to coordinate with the Director and the 69 Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of 70 Chapter 25.1 (§ 54.1-2515 et seq.). Each health regulatory board shall appoint one such designee.

71 9. To take appropriate disciplinary action for violations of applicable law and regulations, and to accept, 72 in their discretion, the surrender of a license, certificate, registration, permit, or multistate licensure privilege 73 in lieu of disciplinary action.

74 10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than 75 two members of the Board and one member of the relevant advisory board, or, when required for special 76 77 conference committees of the Board of Nursing, not less than one member of the Board and one member of 78 the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner or permit holder of the appropriate board may be subject to disciplinary action or to consider an 79 80 application for a license, certification, registration, permit, or multistate licensure privilege in nursing. The special conference committee may (i) exonerate; (ii) reinstate; (iii) place the practitioner or permit holder on 81 82 probation with such terms as it may deem appropriate; (iv) reprimand; (v) modify a previous order; (vi) impose a monetary penalty pursuant to § 54.1-2401, (vii) deny or grant an application for licensure, 83 84 certification, registration, permit, or multistate licensure privilege; and (viii) issue a restricted license, 85 certification, registration, permit, or multistate licensure privilege subject to terms and conditions. The order 86 of the special conference committee shall become final 30 days after service of the order unless a written 87 request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written 88 request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 89 90 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit 91 the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001 92 , the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019. The 93 recommendation of such subordinate may be considered by a panel consisting of at least five board members, 94 or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for 95 the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth 96 in regulations adopted by the board.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the 97 98 board is less than five members, consisting of a quorum of the members to conduct formal proceedings 99 pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by 100 majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal 101 proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings 102 103 pursuant to § 2.2-4020 to consider the same matter.

104 12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such 105 regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates. 106

13. To meet by telephone conference call to consider settlement proposals in matters pending before 107 special conference committees convened pursuant to this section, or matters referred for formal proceedings 108 pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of 109 previously issued board orders when such considerations have been requested by either of the parties. 110

14. To request and accept a confidential consent agreement, in lieu of disciplinary action, from a certified, 111 registered, or licensed practitioner; a facility holding a license, certification, registration, or permit; or a 112 person holding a multistate licensure privilege to practice nursing, in lieu of disciplinary action, a confidential 113 consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 114 54.1-2400.2 and shall not be disclosed by a practitioner or facility. A confidential consent agreement shall 115 116 include findings of fact and may include an admission or a finding of a violation. A confidential consent 117 agreement shall not be considered either a notice or order of any health regulatory board, but it may be 118 considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered 119 into only in cases involving minor misconduct where there is little or no injury to a patient or the public and

120 little likelihood of repetition by the practitioner or facility. A board shall not enter into a confidential consent 121 agreement if there is probable cause to believe the practitioner or facility has (i) demonstrated gross 122 negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as 123 to be a danger to the health and welfare of his patients or the public. A certified, registered, or licensed practitioner, a facility holding a license, certification, registration, or permit, or a person holding a multistate 124 125 licensure privilege to practice nursing who has entered into two confidential consent agreements involving a 126 standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation 127 within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the 128 129 presumption that the disciplinary action be made public.

130 15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill 131 and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit 132 to a mental or physical examination. Failure to submit to the examination shall constitute grounds for 133 134 disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to 135 demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of 136 this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice 137 nursing.

## § 54.1-2409. Mandatory suspension or revocation; reinstatement; hearing for reinstatement.

139 A. Upon receipt of documentation by any court or government agency that a person licensed, certified, or registered by a board within the Department of Health Professions has (i) had his license, certificate, or 140 141 registration to practice the same profession or occupation revoked or suspended for reasons other than 142 nonrenewal or accepted for surrender in lieu of disciplinary action in another jurisdiction and has not had his 143 license, certificate, or registration to so practice reinstated within that jurisdiction, unless such revocation, 144 suspension, or surrender was based solely on the disciplinary action of a board within the Department or mandatory suspension by the Director of the Department or (ii) been convicted of a felony or has been 145 146 adjudged incapacitated, the Director shall immediately suspend, without a hearing, the license, certificate, or 147 registration of any person so disciplined, convicted, or adjudged. The Director shall notify such person or his 148 legal guardian, conservator, trustee, committee, or other representative of the suspension in writing to his 149 address on record with the Department. Such notice shall include a copy of the documentation from such 150 court or agency, certified by the Director as the documentation received from such court or agency. Such 151 person shall not have the right to practice within this the Commonwealth until his license, certificate, or 152 registration has been reinstated by the Board relevant board within the Department of Health Professions.

- 153 B. The clerk of any court in which a conviction of a felony or an adjudication of incapacity is made, who has knowledge that a person licensed, certified, or registered by a board within the Department has been 154 convicted or found incapacitated, shall have a duty to report these findings promptly to the Director. 155
- 156 C. When a conviction has not become final, the Director may decline to suspend the license, certificate, or 157 registration until the conviction becomes final if there is a likelihood of injury or damage to the public if the 158 person's services are not available.

159 D. Any person whose license, certificate, or registration has been suspended as provided in this section 160 may apply to the board for reinstatement of his license, certificate, or registration. Such person shall be entitled to a hearing not later than the next regular meeting of the board after the expiration of 60 days from 161 the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses 162 to testify in his behalf. The **Board** board may consider other information concerning possible violations of 163 164 Virginia law at such hearing, if reasonable notice is given to such person of the information.

165 The reinstatement of the applicant's license, certificate, or registration shall require the affirmative vote of 166 three-fourths of the members of the board at the hearing. The board may order such reinstatement without further examination of the applicant, or reinstate the license, certificate, or registration upon such terms and 167 168 conditions as it deems appropriate.

E. Pursuant to the authority of the Board of Nursing provided in Chapter 30 (§ 54.1-3000 et seq.) of this 169 170 title, the provisions of this section shall apply, mutatis mutandis, to persons holding a multistate licensure 171 privilege to practice nursing. 172

## § 54.1-2410. Definitions.

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173 As used in this chapter or when referring to the Board Department of Health Professions regulatory 174 authority therefor, unless the context requires a different meaning:

#### 175 "Board" means the Board of Health Professions.

"Community" means a city or a county.

177 "Demonstrated need" means (i) there is no facility in the community providing similar services and (ii) 178 alternative financing is not available for the facility, or (iii) such other conditions as may be established by 179 Board Department regulation.

180 "Department" means the Department of Health Professions.

181 "Entity" means any person, partnership, firm, corporation, or other business, including assisted living

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182 facilities as defined in § 63.2-100, that delivers health services.

"Group practice" means two or more health care practitioners who are members of the same legally 183 organized partnership, professional corporation, not-for-profit corporation, faculty practice or similar 184

association in which (i) each member provides substantially the full range of services within his licensed or 185 certified scope of practice at the same location as the other members through the use of the organization's 186

office space, facilities, equipment, or personnel; (ii) payments for services received from a member are 187

treated as receipts of the organization; and (iii) the overhead expenses and income from the practice are 188 distributed according to methods previously determined by the members. 189

"Health services" means any procedures or services related to prevention, diagnosis, treatment, and care 190 191 rendered by a health care worker, regardless of whether the worker is regulated by the Commonwealth.

192 "Immediate family member" means the individual's spouse, child, child's spouse, stepchild, stepchild's 193 spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling.

194 "Investment interest" means the ownership or holding of an equity or debt security, including, but not 195 limited to, shares of stock in a corporation, interests or units of a partnership, bonds, debentures, notes, or other equity or debt instruments, except investment interests in a hospital licensed pursuant to Article 1 (§ 196 197 32.1-123 et seq.) of Chapter 5 of Title 32.1.

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership 198 199 interest, including an investment interest.

"Office practice" means the facility or facilities at which a practitioner, on an ongoing basis, provides or 200 supervises the provision of health services to consumers. 201

"Practitioner" means any individual certified or licensed by any of the health regulatory boards within the 202 Department of Health Professions, except individuals regulated by the Board of Funeral Directors and 203 Embalmers or the Board of Veterinary Medicine. 204

"Referral" means to send or direct a patient for health services to another health care practitioner or entity 205 206 outside the referring practitioner's group practice or office practice or to establish a plan of care which requires the provision of any health services outside the referring practitioner's group practice or office 207 208 practice. 209

## § 54.1-2411. Prohibited referrals and payments; exceptions.

210 A. Unless the practitioner directly provides health services within the entity and will be personally 211 involved with the provision of care to the referred patient, or has been granted an exception by the Board Department or satisfies the provisions of subsections D or E of this section or of subsections D or E of § 212 213 54.1-2413, a practitioner shall not refer a patient for health services to an entity outside the practitioner's office or group practice if the practitioner or any of the practitioner's immediate family members is an 214 215 investor in such entity.

B. The Board Department may grant an exception to the prohibitions in this chapter, and may permit a 216 217 practitioner to invest in and refer to an entity, regardless of whether the practitioner provides direct services within such entity, if there is a demonstrated need in the community for the entity and all of the following 218 219 conditions are met:

1. Individuals other than practitioners are afforded a bona fide opportunity to invest in the entity on the 220 221 same and equal terms as those offered to any referring practitioner;

2. No investor-practitioner is required or encouraged to refer patients to the entity or otherwise generate 222 223 business as a condition of becoming or remaining an investor;

224 3. The services of the entity are marketed and furnished to practitioner-investors and other investors on 225 the same and equal terms;

226 4. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer 227 patients to such entity;

5. The income on the practitioner's investment is based on the practitioner's equity interest in the entity 228 229 and is not tied to referral volumes; and

230 6. The investment contract between the entity and the practitioner does not include any covenant or clause 231 limiting or preventing the practitioner's investment in other entities.

Unless the Board Department, the practitioner, or the entity requests a hearing, the Board Department 232 233 shall determine whether to grant or deny an exception within 90 days of the receipt of a written request from the practitioner or entity, stating the facts of the particular circumstances and certifying compliance with the 234 conditions required by this subsection. The Board's Department's decision shall be a final administrative 235 236 decision and shall be subject to judicial review pursuant to the Administrative Process Act (§ 2.2-4000 et 237 seq.). 238

C. When an exception is granted pursuant to subsection B:

239 1. The practitioner shall disclose his investment interest in the entity to the patient at the time of referral. 240 If alternative entities are reasonably available, the practitioner shall provide the patient with a list of such 241 alternative entities and shall inform the patient of the option to use an alternative entity. The practitioner shall also inform the patient that choosing another entity will not affect his treatment or care; 242

243 2. Information on the practitioner's investment shall be provided if requested by any third party payor; 244 3. The entity shall establish and utilize an internal utilization review program to ensure that practitioner-245 investors are engaging in appropriate and necessary utilization; and

4. In the event of a conflict of interests between the practitioner's ownership interests and the best interests 246 247 of any patient, the practitioner shall not make a referral to such entity, but shall make alternative 248 arrangements for the referral.

249 D. Further, a practitioner may refer patients for health services to a publicly traded entity in which such 250 practitioner has an investment interest, without applying for or receiving an exception from the Board, 251 *Department* if all of the following conditions are met:

1. The entity's stock is listed for trading on the New York Stock Exchange or the American Stock 252 253 Exchange or is a national market system security traded under an automated interdealer quotation system 254 operated by the National Association of Securities Dealers;

255 2. The entity had, at the end of the corporation's most recent fiscal year, total net assets of at least 256 \$50,000,000 \$50 million related to the furnishing of health services;

257 3. The entity markets and furnishes its services to practitioner-investors and other practitioners on the 258 same and equal terms;

259 4. All stock of the entity, including the stock of any predecessor privately held company, is one class 260 without preferential treatment as to status or remuneration;

5. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer 261 patients to such entity; 262

6. The income on the practitioner's investment is not tied to referral volumes and is based on the 263 264 practitioner's equity interest in the entity; and

265 7. The practitioner's investment interest does not exceed one half one-half of one percent of the entity's 266 total equity.

267 E. In addition, a practitioner may refer a patient to such practitioner's immediate family member or such 268 immediate family member's office or group practice for health services if all of the following conditions are 269 met:

1. The health services to be received by the patient referred by the practitioner are within the scope of 270 271 practice of the practitioner's immediate family member or the treating practitioner within such immediate 272 family member's office or group practice;

273 2. The practitioner's immediate family member or the treating practitioner within such immediate family member's office or group practice is qualified and duly licensed to provide the health services to be received 274 275 by the patient referred to the practitioner;

3. The primary purpose of any such referral is to obtain the appropriate professional health services for the 276 277 patient being referred, which are to be rendered by the referring practitioner's immediate family member or by the treating practitioner within such immediate family member's office or group practice who is qualified 278 279 and licensed to provide such professional health services; and

280 4. The primary purpose of the referral shall not be for the provision of designated health services as 281 defined in 42 U.S.C. § 1395nn and the regulations promulgated thereunder. 282

## § 54.1-2412. Department to administer; powers and duties of Department; penalties for violation.

283 A. In addition to its other powers and duties, the **Board** Department of Health Professions shall administer 284 the provisions of this chapter.

285 B. The Board Department shall promulgate, pursuant to the Administrative Process Act (§ 2.2-4000 et 286 seq.), regulations to:

287 1. Establish standards, procedures, and criteria which are reasonable and necessary for the effective 288 administration of this chapter;

289 2. Establish standards, procedures, and criteria for determining compliance with, exceptions to, and 290 violations of the provisions of § 54.1-2411;

291 3. Establish standards, procedures, and criteria for advising practitioners and entities of the applicability of 292 this chapter to activities and investments;

293 4. Levy and collect fees for processing requests for exceptions from the prohibitions set forth in this 294 chapter and for authorization to make referrals pursuant to subsection B of § 54.1-2411;

295 5. Establish standards, procedures, and criteria for review and referral to the appropriate health regulatory 296 board of all reports of investigations of alleged violations of this chapter by practitioners and for 297 investigations and determinations of violations of this chapter by entities;

298 6. Establish standards, procedures, and criteria for granting exceptions from the prohibitions set forth in 299 this chapter; and

7. Establish such other regulations as may reasonably be needed to administer this chapter.

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301 C. Upon a determination of a violation by the Board Department, pursuant to the Administrative Process 302 Act, any entity, other than a practitioner, that presents or causes to be presented a bill or claim for services 303 that the entity knows or has reason to know is prohibited by § 54.1-2411 shall be subject to a monetary penalty of no more than \$20,000 per referral, bill, or claim. The monetary penalty may be sued for and 304

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305	recovered in the name of the Commonwealth. All such monetary penalties shall be deposited in the Literary
306	Fund.
307	D. Any violation of this chapter by a practitioner shall constitute grounds for disciplinary action as
308	unprofessional conduct by the appropriate health regulatory board within the Department of Health
309	Professions. Sanctions for violation of this chapter may include, but are not limited to, the monetary penalty
310	authorized in § 54.1-2401.
311	§ 54.1-2500. Definitions.
312	As used in this chapter, unless the context requires a different meaning:
313	"Board" means the Board of Health Professions.
314	"Department" means the Department of Health Professions.
315	"Director" means the Director of the Department of Health Professions.
316	"Health regulatory board" or "regulatory board" means any board included within the Department of
317	Health Professions as provided in § 54.1-2503.
318	§ 54.1-2503. Boards within Department.
319	In addition to the Board of Health Professions, the The following boards are included within the
320	Department: Board of Audiology and Speech-Language Pathology, Board of Counseling, Board of Dentistry,
321	Board of Funeral Directors and Embalmers, Board of Long-Term Care Administrators, Board of Medicine,
322	Board of Nursing, Board of Optometry, Board of Pharmacy, Board of Physical Therapy, Board of
323	Psychology, Board of Social Work, and Board of Veterinary Medicine.
324	§ 54.1-2505. Powers and duties of Director of Department.
325	The Director of the Department shall have the following powers and duties:
326	1. To supervise and manage the Department;
327	2. To perform or consolidate such administrative services or functions as may assist the operation of the
328	boards;
329	3. To prepare, approve, and submit to the Governor, after consultation with the boards, all requests for
330	appropriations and be responsible for all expenditures pursuant to appropriations;
331	4. To provide such office facilities as will allow the boards to carry out their duties;
332	5. To employ personnel as required for the proper performance of the responsibilities of the Department
333	subject to Chapter 29 the Virginia Personnel Act (§ 2.2-2900 et seq.) of Title 2.2 within the limits of
334	appropriations made by law;
335	6. To receive all complaints made against regulated health care professionals;
336	7. To develop administrative policies and procedures governing the receipt and recording of complaints;
337	8. To monitor the status of actions taken under the auspices of the boards regarding complaints until the
338	closure of each case;
339	9. To provide investigative and such other services as needed by the boards to enforce their respective
340	statutes and regulations;
341	10. To provide staff to assist in the performance of the duties of the Board of Health Professions;
342 343	11. To collect and account for all fees to be paid into each board and account for and deposit the moneys so collected into a special fund from which the expenses of the health regulatory boards, the Health
343 344	Practitioners' Monitoring Program, and the Department and Board of Health Professions shall be paid. Such
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343 346	fees shall be held exclusively to cover the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department and Board of Health Professions and shall not be transferred to any
347	agency other than the Department of Health Professions, except as provided in §§ 54.1-3011.1 and
348	54.1-3011.2;
349	12. 11. To make and enter into all contracts and agreements necessary or incidental to the performance of
350	his duties and the execution of his powers, including, but not limited to, contracts with the United States,
351	other states, <i>and</i> agencies and governmental subdivisions of the Commonwealth;
352	13. 12. To accept grants from the United States government, its agencies and instrumentalities, and any
353	other source. The Director shall have the power to comply with conditions and execute agreements as may be
354	necessary, convenient, or desirable:

14. 13. To promulgate and revise regulations necessary for the administration of the Department and such 355 regulations as are necessary for the implementation of the Health Practitioners' Monitoring Program pursuant 356 to Chapter 25.1 (§ 54.1-2515 et seq.) of this title and subdivision 19 of this section 18; 357

15. 14. To report promptly, after consultation with the presiding officer of the appropriate health 358 359 regulatory board or his designee, to the Attorney General or the appropriate attorney for the Commonwealth any information the Department obtains which, upon appropriate investigation, indicates, in the judgment of 360 the Director, that a person licensed by any of the health regulatory boards has violated any provision of 361 criminal law, including the laws relating to manufacturing, distributing, dispensing, prescribing, or 362 administering drugs other than drugs classified as Schedule VI drugs. When necessary, the Attorney General 363 or the attorney for the Commonwealth shall request that the Department of Health Professions or the 364 Department of State Police conduct any subsequent investigation of such report. Upon request and affidavit 365

366 from an attorney for the Commonwealth, the Director shall provide documents material to a criminal 367 investigation of a person licensed by a health regulatory board; however, peer review documents shall not be 368 released and shall remain privileged pursuant to § 8.01-581.17. For the purpose of this section, the terms

369 manufacturing, distributing, dispensing, prescribing, or administering drugs shall not include minor

- 370 administrative or clerical errors which that do not affect the inventory of drugs required by Chapter 34 the
- 371 Drug Control Act (§ 54.1-3400 et seq.) of this title and do not indicate a pattern of criminal behavior; 372
  - 16. 15. To keep records of the names and qualifications of registered, certified, or licensed persons;
- 373 17. 16. To exercise other powers and perform other duties required of the Director by the Governor; 374 18. 17. To issue subpoenas in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) for any
- 375 informal fact finding or formal proceeding within the jurisdiction of the Department or any regulatory board; 376 19. 18. To establish, and revise as necessary, a health practitioners' monitoring program pursuant to
- 377 Chapter 25.1 (§ 54.1-2515 et seq.) of this title;
- 378  $\frac{20}{20}$ . 19. To establish, and revise as necessary, with such federal funds, grants, or general funds as may be 379 appropriated or made available for this program, the Prescription Monitoring Program pursuant to Chapter 380 25.2 (§ 54.1-2519 et seq.) of this title; and
- 381 21. 20. To assess a civil penalty against any person who is not licensed by a health regulatory board for 382 failing to report a violation pursuant to § 54.1-2400.6 or § 54.1-2909;
- 383 21. To evaluate, at the request of the General Assembly, health care professions and occupations in the 384 Commonwealth and to consider whether each such profession or occupation should be regulated and the 385 degree of regulation to be imposed;
- 386 22. To receive, review, and forward to the appropriate health regulatory board, any departmental 387 investigative reports relating to complaints of violations by practitioners of the Practitioner Self-Referral Act 388 (§ 54.1-2410 et seq.);
- 389 23. To determine compliance with, violations of, and grant exceptions to the prohibitions set forth in the 390 Practitioner Self-Referral Act (§ 54.1-2410 et seq.); and
- 391 24. To take appropriate actions against entities, other than practitioners, for violations of the Practitioner Self-Referral Act (§ 54.1-2410 et seq.). 392
- 393 § 54.1-2506. Enforcement of laws by Director and investigative personnel; authority of investigative 394 personnel and Director.
- 395 A. The Director and investigative personnel appointed by him shall be sworn to enforce the statutes and 396 regulations pertaining to the Department, the Board, and the health regulatory boards and shall have the 397 authority to investigate any violations of those statutes and regulations and to the extent otherwise authorized 398 by law inspect any office or facility operated, owned or employing individuals regulated by any health 399 regulatory board. The Director or his designee shall have the power to subpoena witnesses and to request and 400 obtain patient records, business records, papers, and physical or other evidence in the course of any 401 investigation or to issue subpoenas requiring the production of such evidence. A subpoena issued pursuant to 402 this section may be served by (i) any person authorized to serve process under § 8.01-293, (ii) investigative personnel appointed by the Director, (iii) registered or certified mail or by equivalent commercial parcel 403 404 delivery service, or (iv) email or facsimile if requested to do so by the recipient. Upon failure of any person to 405 comply with a subpoena duly served, the Director may, pursuant to § 54.1-111, request that the Attorney General or the attorney for the Commonwealth for the jurisdiction in which the recipient of the subpoena 406 407 resides, is found, or transacts business seek enforcement of the subpoena in such jurisdiction.
- 408 B. All investigative personnel shall be vested with the authority to (i) administer oaths or affirmations for 409 the purpose of receiving complaints of violations of this subtitle, (ii) serve and execute any warrant, paper or 410 process issued by any court or magistrate, the Board, the Director or in his absence a designated subordinate, 411 or by any regulatory board under the authority of the Director, (iii) request and receive criminal history information under the provisions of § 19.2-389, and (iv) request and receive social security numbers from 412 413 practitioners or federal employee identification numbers from facilities.
- 414 C. The Director shall have the authority to issue summonses for violations of statutes and regulations governing the unlicensed practice of professions regulated by the Department. The Director may delegate 415 416 such authority to investigators appointed by him. In the event a person issued such a summons fails or refuses 417 to discontinue the unlawful acts or refuses to give a written promise to appear at the time and place specified 418 in the summons, the investigator may appear before a magistrate or other issuing authority having jurisdiction 419 to obtain a criminal warrant pursuant to § 19.2-72.

#### 420 § 54.1-2729.2. Dialysis patient care technician; definition.

"Dialysis patient care technician" or "dialysis care technician" means a person who has obtained 421 422 certification from an organization approved by the **Board** Department of Health Professions to provide, under 423 the supervision of a licensed practitioner of medicine or a registered nurse, direct care to patients undergoing 424 renal dialysis treatments in a Medicare-certified renal dialysis facility. Such direct care may include, but need 425 not be limited to, the administration of heparin, topical needle site anesthetics, dialysis solutions, sterile 426 normal saline solution, and blood volumizers in accordance with the order of a licensed physician, an

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427 advanced practice registered nurse, or a physician assistant. However, a person who has completed a training

428 program in dialysis patient care may engage in provisional practice to obtain practical experience in 429 providing direct patient care under direct and immediate supervision in accordance with § 54.1-3408, until he

has taken and received the results of any examination required by a certifying organization approved by the 430

Board or for 24 months from the date of initial practice, whichever occurs sooner. 431

#### § 54.1-2729.3. Prohibition on use of title without holding certification; continuing competency 432 433 requirements; fees; penalty.

A. No person shall hold himself out to be or advertise or permit to be advertised that he is a dialysis 434 patient care technician or dialysis care technician as defined in this chapter unless such person has obtained 435 436 certification from an organization approved by the **Board** Department of Health Professions as examining 437 candidates for appropriate competency or technical proficiency to perform as dialysis patient care technicians 438 or dialysis care technicians.

439 B. The title restrictions provided by this section shall apply to the use of the terms "dialysis patient care technician" and "dialysis care technician" or any other term or combination of terms used alone or in combination with the terms "licensed," "certified," or "registered," as such terms also imply a minimum level 440 441 of education, training, and competence. A person who is authorized for provisional practice to provide direct 442 patient care while obtaining practical experience shall be identified as a "trainee" while working in a renal 443 444 dialysis facility.

C. The Board Department of Health Professions may require such continuing competency training as it 445 may deem necessary for dialysis patient care technicians or dialysis care technicians. 446

D. Any person who willfully violates the provisions of this chapter shall be is guilty of a Class 3 447 **448** misdemeanor. 449

## § 54.1-2731. Prohibited terms; penalty.

A. As used in this section, "nutritional genomics" means the consideration of biochemical or genetic 450 information to evaluate how genetics affect gene function and how genetic variation alters nutrient response, 451 including the study of how dietary and other lifestyle choices influence the function of humans at the 452 453 molecular, cellular, organismal, and populational levels.

454 B. No person shall hold himself out to be or advertise or permit to be advertised that such person is a 455 dietitian or nutritionist unless such person:

1. Has (i) received a baccalaureate or higher degree in nutritional sciences, community nutrition, public 456 health nutrition, food and nutrition, dietetics, or human nutrition from a regionally accredited institution of 457 higher education and (ii) satisfactorily completed a program of supervised clinical experience approved by 458 the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics; 459

2. Has active registration through the Commission on Dietetic Registration of the Academy of Nutrition 460 461 and Dietetics:

462 3. Has an active certificate of the Board for Certification of Nutrition Specialists as a Certified Nutrition 463 Specialist;

4. Has an active certification as a Diplomate of the American Clinical Board of Nutrition;

5. Has a current license or certificate as a dietitian or nutritionist issued by another state; or

6. Has the minimum requisite education, training and experience determined by the Board Department of 466 Health Professions appropriate for such person to hold himself out to be, or advertise or allow himself to be 467 468 advertised as, a dietitian or nutritionist.

469 The restrictions of this section apply to the use of the terms "dietitian" and "nutritionist" as used alone or in any combination with the terms "licensed," "certified," or "registered," as those terms also imply a 470 471 minimum level of education, training and competence.

C. Any person who meets the requirements set forth in subsection B who receives nutritional genomics 472 testing information shall maintain such information in accordance with applicable federal and state law. 473

474 D. A person who does not meet the requirements of subsection B but who (i) has a baccalaureate degree 475 with a major in food and nutrition or dietetics or has equivalent hours of food and nutrition coursework and (ii) has two years of work experience in nutrition or dietetics concurrent with or subsequent to completion of 476 477 such degree may hold himself out as a dietitian or nutritionist, provided he is employed by or under contract 478 to a government agency and practices solely within the scope of such employment.

E. Any person who willfully violates the provisions of this section is guilty of a Class 3 misdemeanor.

## § 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, 482 ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his 483 484 authorized agent and under his direction or (ii) the patient or research subject at the direction and in the 485 presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by 486 labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of 487

488 drugs or devices.

489 "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, 490 distributor, or dispenser. "Agent" does not include a common or contract carrier, public warehouseman, or 491 employee of the carrier or warehouseman.

492 'Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to 493 testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone. 494

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

495 "Automated drug dispensing system" means a mechanical or electronic system that performs operations or 496 activities, other than compounding or administration, relating to pharmacy services, including the storage, 497 dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction 498 information, to provide security and accountability for such drugs.

499 "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component 500 or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, 501 502 applicable to the prevention, treatment, or cure of a disease or condition of human beings.

503 "Biosimilar" means a biological product that is highly similar to a specific reference biological product, 504 notwithstanding minor differences in clinically inactive compounds, such that there are no clinically 505 meaningful differences between the reference biological product and the biological product that has been 506 licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product. 507 "Board" means the Board of Pharmacy.

508 "Bulk drug substance" means any substance that is represented for use, and that, when used in the 509 compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" does not include intermediates that are used in the 510 511 synthesis of such substances.

512 "Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the 513 sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls 514 the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or a change 515 in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of 516 voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary 517 owning the entity, except that this shall not apply to any corporation the voting stock of which is actively 518 traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning 519 the entity or of the parent corporation of a wholly-owned wholly owned subsidiary owning the entity with 520 another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

521 "Co-licensed partner" means a person who, with at least one other person, has the right to engage in the 522 manufacturing or marketing of a prescription drug, consistent with state and federal law.

523 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a 524 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or 525 526 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in 527 expectation of receiving a valid prescription based on observed historical patterns of prescribing and 528 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an 529 incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of 530 his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis 531 and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs 532 for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy 533 licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to 534 subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed advanced 535 practice registered nurse or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be 536 considered compounding.

537 "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this 538 chapter. "Controlled substance" does not include distilled spirits, wine, malt beverages, or tobacco as those 539 terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled 540 substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority 541 in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar 542 543 to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, 544 depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater 545 than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled 546 substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or 547 intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is 548 substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central

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549 nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include 550 (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective 551 552 pursuant to §§ 501, 502, and 503 of the federal Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an 553 exemption is in effect for investigational use for that person under § 505 of the federal Federal Food, Drug, 554 555 and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; 556 or (c) any substance to the extent not intended for human consumption before such an exemption takes effect 557 with respect to that substance.

558 "DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this 559 chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI prescription 560 device to an ultimate user or consumer on behalf of a medical equipment supplier by a manufacturer, 561 nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident 562 563 warehouser, third-party logistics provider, or nonresident third-party logistics provider at the direction of a 564 medical equipment supplier in accordance with § 54.1-3415.1.

565 "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or 566 animals or to affect the structure or any function of the body of man or animals. 567

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an 568 organization approved by the Board Department of Health Professions pursuant to Chapter 27.01 (§ 569 570 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, an advanced practice registered nurse, a physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis 571 572 treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is 573 to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or 574 commercially available solutions whose purpose is to be used in the performance of hemodialysis not to 575 576 include any solutions administered to the patient intravenously.

577 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, "dispensing" does not include the 578 579 580 transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to 581 582 patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" includes only the provision of drugs by a practitioner to patients to take 583 584 with them away from the practitioner's place of practice. 585

- "Dispenser" means a practitioner who dispenses. "Distribute" means to deliver other than by administering or dispensing a controlled substance.
  - "Distributor" means a person who distributes.

588 "Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; 589 590 (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of 591 disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any 592 function of the body of man or animals; (iv) articles or substances intended for use as a component of any 593 article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their 594 components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by 595 596 brand or therapeutically equivalent drug product name.

597 "Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted 598 in accordance with 21 C.F.R. Part 1300. 599

600 "Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form. 601 602

"FDA" means the U.S. Food and Drug Administration.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation 603 designates as being the principal compound commonly used or produced primarily for use, and which is an 604 immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the 605 606 control of which is necessary to prevent, curtail, or limit manufacture.

607 "Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4). 608

609 "Label" means a display of written, printed, or graphic matter upon the immediate container of any article.

610 A requirement made by or under authority of this chapter that any word, statement, or other information

611 appear on the label shall not be considered to be complied with unless such word, statement, or other 612 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.

614 "Labeling" means all labels and other written, printed, or graphic matter on an article or any of its615 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.
"Manufacture" does not include compounding.

621 "Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a 622 repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its 623 624 resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the mature stalks 625 626 of such plant, fiber produced from such stalk, or 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; (ii) industrial hemp, as 627 defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his 628 agent; (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp 629 producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990; (iv) a hemp 630 631 product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any 632 substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 633 634 54.1-3400 et seq.) pursuant to § 54.1-3443.

<sup>635</sup> "Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the
<sup>636</sup> ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles,
<sup>637</sup> medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no
<sup>638</sup> medicinal properties that are used for the operation and cleaning of medical equipment, solutions for
<sup>639</sup> peritoneal dialysis, and sterile water or saline for irrigation.

640 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from 641 substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of 642 extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of 643 opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically 644 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; or (iv) coca leaves and any salt, compound, 645 derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof 646 647 which is chemically equivalent or identical with any of these substances, but not including decocainized coca 648 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 649 650 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 651 652 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 653 654 chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its 655 labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a 656 new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is 657 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 658 659 a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the AmericanRegistry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

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

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

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to
morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining
liability. "Opiate" does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437)

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et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan).
"Opiate" does include its racemic and levorotatory forms.

<sup>673</sup> "Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

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

677 "Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently
678 registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies
679 with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act
680 , 21 U.S.C. § 301 et seq.

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

<sup>683</sup> "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a
<sup>684</sup> pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner
<sup>685</sup> complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of
<sup>686</sup> controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the
<sup>687</sup> pharmacy's personnel as required by § 54.1-3432.

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

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

695 "Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a696 prescription.

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

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

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

706 "Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original 707 package which does not contain any controlled substance or marijuana as defined in this chapter and is not in 708 itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol 709 710 privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, "proprietary medicine" does not include a drug that is only advertised or promoted 711 712 professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed 713 only upon prescription or the label of which bears substantially the statement "Warning — may be habitforming," or a drug intended for injection. 714

715 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with 716 the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide 717 generator that is intended to be used in the preparation of any such substance, but does not include drugs such 718 as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally 719 occurring radionuclides. "Radiopharmaceutical" also includes any biological product that is labeled with a 720 radionuclide or intended solely to be labeled with a radionuclide.

721 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. §
722 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug
723 Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. §
724 262(k).

"Remote dispensing system" means a profile-driven automated drug dispensing system that performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient, authorized agent of the patient, or person licensed to administer drugs, and collects, controls, and maintains all information online. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and Board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer

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732 drugs.

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"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, 733 734 whether as an individual, proprietor, agent, servant, or employee.

735 "Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its 736 salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is 737 possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, 738 739 "isomer" means the optical, position, and geometric isomers.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients 740 741 and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of 742 743 "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products 744 with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

745 "Third-party logistics provider" means a person that provides or coordinates warehousing of or other 746 logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale 747 distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product. 748

749 'Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of 750 the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic 751 acid.

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

753 "Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics 754 provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or devices to any 755 person who is not the ultimate user or consumer and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be subject to any state or local tax by 756 757 reason of this definition.

"Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers or 758 759 patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer pursuant to § 760 54.1-3415.1, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

761 "Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, 762 a third-party logistics provider, or a repackager that engages in wholesale distribution.

763 The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter do not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for 764 765 the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter have the same 766 meanings as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning. 767 768

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced 769 practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, 770 a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 771 772 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife 773 774 pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for 775 medicinal or therapeutic purposes within the course of his professional practice.

776 B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription 777 as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or 778 devices to be administered by: 779

1. A nurse, physician assistant, or intern under his direction and supervision;

780 2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of 781 Behavioral Health and Developmental Services who administer drugs under the control and supervision of 782 783 the prescriber or a pharmacist;

784 3. Emergency medical services personnel certified and authorized to administer drugs and devices 785 pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to 786 an oral or written order or standing protocol;

787 4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a 788 valid emergency medical services provider certification issued by the Board of Health as a requirement of 789 being employed or engaged at the medical care facility within the scope of such certification, pursuant to an 790 oral or written order or standing protocol to administer drugs and devices at the medical care facility; or

791 5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled 792 substances used in inhalation or respiratory therapy.

793 C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or

federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a
nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the
diagnosis or treatment of disease.

797 D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of
798 his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to
799 possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii)
800 heparin and sterile normal saline to use for the maintenance of intravenous access lines.

801 Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may802 possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional
 practice, any school nurse, school board employee, employee of a local governing body, or employee of a
 local health department who is authorized by a prescriber and trained in the administration of epinephrine
 may possess and administer epinephrine.

807 Pursuant to an order or standing protocol that shall be issued by the local health director within the course 808 of his professional practice, any school nurse, licensed athletic trainer under contract with a local school 809 division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol 810 811 inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an 812 813 albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience 814 an asthmatic crisis.

815 Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the 816 817 Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in 818 the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or 819 nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student 820 821 diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed 822 to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional
practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a
local health department who is authorized by a prescriber and trained in the administration of epinephrine
may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional
practice, any employee of a public institution of higher education or a private institution of higher education
who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer
epinephrine.

831 Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional
832 practice, any employee of an organization providing outdoor educational experiences or programs for youth
833 who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer
834 epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional
practice, and in accordance with policies and guidelines established by the Department of Health, such
prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of
Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is
employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of
a provider licensed by the Department of Behavioral Health and Developmental Services or a person
providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health
and Developmental Services may possess and administer epinephrine, provided such person is authorized and
trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional
practice, any employee of a place of public accommodation, as defined in subsection A of § 2.2-3904, who is
authorized by a prescriber and trained in the administration of epinephrine may possess and administer
epinephrine.

849 Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his
850 professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for
851 administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of
 his professional practice, such prescriber may authorize licensed physical therapists to possess and administer
 topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

**F.** Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of

his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer
topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in
emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of
anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

860 G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of 861 Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses 862 under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative 863 864 (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing 865 866 transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor 867 and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. 868 Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be 869 870 administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The 871 prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in 872 the practice and principles underlying tuberculin screening.

873 The Health Commissioner or his designee may authorize registered nurses, acting as agents of the
874 Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein
875 derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies
876 established by the Department of Health.

877 H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his 878 professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an 879 employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by 880 the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the 881 Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist 882 with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who 883 requires insulin injections during the school day or for whom glucagon has been prescribed for the 884 emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an 885 advanced practice registered nurse, a physician, or a physician assistant is not present to perform the 886 administration of the medication.

887 Pursuant to a written order or standing protocol issued by the prescriber within the course of his
888 professional practice, such prescriber may authorize the possession and administration of undesignated
889 glucagon as set forth in subsection F of § 22.1-274.2.

890 Pursuant to a written order or standing protocol issued by the prescriber within the course of his 891 professional practice, such prescriber may authorize an employee of a public institution of higher education 892 or a private institution of higher education who is trained in the administration of insulin and glucagon to 893 assist with the administration of insulin or administration of glucagon to a student diagnosed as having 894 diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency 895 treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced 896 practice registered nurse, a physician, or a physician assistant is not present to perform the administration of 897 the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such
 prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and
 Developmental Services or a person providing services pursuant to a contract with a provider licensed by the
 Department of Behavioral Health and Developmental Services to assist with the administration of insulin or
 to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for
 whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee
 or person providing services has been trained in the administration of insulin and glucagon.

905 I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the 906 administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not 907 physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under 908 the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established 909 protocols of the Department of Health may authorize the administration of vaccines to any person by a 910 pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when 911 912 the prescriber is not physically present. The emergency medical services provider shall provide 913 documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervisionby either a dental hygienist or by an authorized agent of the dentist.

916 Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the

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917 course of his professional practice, a dentist may authorize a dental hygienist under his general supervision,

**918** as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied

antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug
 approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

825 K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of
826 his professional practice, such prescriber may authorize registered professional nurses certified as sexual
827 assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess
828 and administer preventive medications for victims of sexual assault as recommended by the Centers for
829 Disease Control and Prevention.

930 L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed 931 a training program for this purpose approved by the Board of Nursing and who administers such drugs in 932 accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record 933 934 keeping, when the drugs administered would be normally self-administered by (i) an individual receiving 935 services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility 936 approved by the Board or Department of Juvenile Justice for the placement of children in need of services or 937 938 delinquent or alleged delinquent youth; (iv) a program participant of an adult day center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local 939 940 government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, 941 942 Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education. 943

In addition, this section shall not prevent a person who has successfully completed a training program for
the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been
evaluated by a registered nurse as having demonstrated competency in administration of drugs via
percutaneous gastrostomy tube from administering drugs to a person receiving services from a program
licensed by the Department of Behavioral Health and Developmental Services to such person via
percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous
gastrostomy tube shall be evaluated semiannually by a registered nurse.

951 M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of 952 Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living 953 facility licensed by the Department of Social Services. A registered medication aide shall administer drugs 954 pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and 955 manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to 956 security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; 957 and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

958 N. In addition, this section shall not prevent the administration of drugs by a person who administers such 959 drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of 960 administration and with written authorization of a parent, and in accordance with school board regulations 961 relating to training, security and record keeping, when the drugs administered would be normally self-962 administered by a student of a Virginia public school. Training for such persons shall be accomplished 963 through a program approved by the local school boards, in consultation with the local departments of health.

964 O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government 965 pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as 966 administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily 967 968 completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of 969 970 medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the 971 972 prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers 973 only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that 974 would normally be self-administered by the child or student, or administered by a parent or guardian to the 975 child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices bypersons if they are authorized by the State Health Commissioner in accordance with protocols established by

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978 the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a 979 state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an 980 actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of 981 Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances 982 dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to 983 the public life and health and for the limited purpose of administering vaccines as an approved 984 countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the 985 provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely 986 administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or 987 devices under the direction, control, and supervision of the State Health Commissioner.

988 Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed989 individuals to a person in his private residence.

8. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

994 S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care 995 technicians who are certified by an organization approved by the **Board** Department of Health Professions or 996 persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary 997 course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle 998 site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of 999 facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a 1000 licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a 1001 patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the 1002 1003 clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee 1004 is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have
 demonstrated competency as evidenced by holding current valid certification from an organization approved
 by the Board Department of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

**1008** T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber
may authorize the administration of controlled substances by personnel who have been properly trained to
assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous,
intrathecal, or epidural administration and the prescriber remains responsible for such administration.

1014 V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic
 1015 medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order
 1016 or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize
the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed
practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical
services provider who holds an advanced life support certificate issued by the Commissioner of Health when
the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by 1022 a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the 1023 1024 dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the 1025 Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a 1026 1027 health care provider providing services in a hospital emergency department, and emergency medical services 1028 personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for 1029 overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to 1030 this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. 1031 Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, 1032 employees of the Office of the Chief Medical Examiner, employees of the Department of General Services 1033 1034 Division of Consolidated Laboratory Services, employees of the Department of Corrections designated by the 1035 Director of the Department of Corrections or designated as probation and parole officers or as correctional 1036 officers as defined in § 53.1-1, employees of the Department of Juvenile Justice designated as probation and 1037 parole officers or as juvenile correctional officers, employees of regional jails, employees of any state agency, 1038 school nurses, local health department employees that are assigned to a public school pursuant to an

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1039 agreement between the local health department and the school board, school board employees who have 1040 completed training and are certified in the administration of an opioid antagonist for overdose reversal by a 1041 program administered or authorized by the Department of Health, other school board employees or 1042 individuals contracted by a school board to provide school health services, and firefighters may also possess 1043 and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or 1044 other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with 1045 protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the 1046 1047 Department of Health.

1048 Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a 1049 prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or 1050 written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the 1051 Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, any person 1052 1053 may possess and administer naloxone or other opioid antagonist used for overdose reversal, other than 1054 naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols 1055 developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of 1056 Health.

1057 Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an 1058 organization that provides services to individuals at risk of experiencing an opioid overdose or training in the 1059 administration of naloxone for overdose reversal may dispense naloxone, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the 1060 1061 Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle 1062 or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental 1063 Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic 1064 1065 needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The 1066 Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The 1067 dispensing may occur at a site other than that of the controlled substance registration provided the entity 1068 possessing the controlled substances registration maintains records in accordance with regulations of the 1069 Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this 1070 subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of 1071 obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection 1072 may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about 1073 to experience a life-threatening opioid overdose.

1074 Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person 1075 who is believed to be experiencing or about to experience a life-threatening opioid overdose. 1076

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his 1077 1078 professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an 1079 employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the 1080 1081 Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such 1082 1083 medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed 1084 to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a 1085 licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to 1086 perform the administration of the medication.

2. That §§ 54.1-2409.2 and 54.1-2507 through 54.1-2510 of the Code of Virginia are repealed. 1087

1088 3. That the regulations of the Board of Health Professions shall be administered by the Department of 1089 Health Professions and shall remain in full force and effect until the Department of Health Professions

1090 promulgates regulations pursuant to this act.