22108061D

HOUSE BILL NO. 1323

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Governor

on April 11, 2022)

(Patron Prior to Substitute—Delegate Orrock)

A BILL to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines. Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia are amended and reenacted

9 1. That §§ 10 as follows:

11 § 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and 12 Human Services pursuant to federal law; administration of plan; contracts with health care 13 providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto.
The Board shall include in such plan:

18 1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21,
19 placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing
20 agencies by the Department of Social Services or placed through state and local subsidized adoptions to
21 the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which 22 23 disregards from countable resources an amount not in excess of \$3,500 for the individual and an amount 24 not in excess of \$3,500 for his spouse when such resources have been set aside to meet the burial 25 expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender 26 27 value of such policies has been excluded from countable resources and (ii) the amount of any other 28 revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of 29 meeting the individual's or his spouse's burial expenses;

30 3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the 31 32 budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the 33 34 house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed \$5,000. In any case in which the 35 definition of home as provided here is more restrictive than that provided in the state plan for medical 36 37 assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and 38 lot used as the principal residence and all contiguous property essential to the operation of the home 39 regardless of value:

40 4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who
41 are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per
42 admission;

43 5. A provision for deducting from an institutionalized recipient's income an amount for the44 maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for 45 payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most 46 current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American 47 Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards **48** for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and 49 50 Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the 51 children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines 52 53 or Standards shall include any changes thereto within six months of the publication of such Guidelines 54 or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were
Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such
family planning services shall begin with delivery and continue for a period of 24 months, if the woman
continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the
purposes of this section, family planning services shall not cover payment for abortion services and no

HB1323H3

1

2

7

8

7/29/22 10:59

60 funds shall be used to perform, assist, encourage or make direct referrals for abortions;

61 8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast 62 63 cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a 64 performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. 65 Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

66 9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate 67 contact information, including the best available address and telephone number, from each applicant for 68 medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant 69 70 for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance 71 72 directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a 73 74 breast for any medical reason. Breast reductions shall be covered, if prior authorization has been 75 obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic; 76

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically 77 78 necessary complete or partial removal of a breast for any medical reason;

79 13. A provision for payment of medical assistance which provides for payment for 48 hours of 80 inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of 81 inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring 82 the provision of inpatient coverage where the attending physician in consultation with the patient 83 84 determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any 85 86 supporting verifiable documentation shall be signed, dated, and returned by the physician, physician 87 assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 88 days from the time the ordered durable medical equipment and supplies are first furnished by the 89 durable medical equipment provider;

90 15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons 91 age 40 and over who are at high risk for prostate cancer, according to the most recent published 92 guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal 93 examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate 94 95 specific antigen;

96 16. A provision for payment of medical assistance for low-dose screening mammograms for 97 determining the presence of occult breast cancer. Such coverage shall make available one screening 98 mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 99 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an 100 X-ray examination of the breast using equipment dedicated specifically for mammography, including but 101 not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average 102 radiation exposure of less than one rad mid-breast, two views of each breast;

103 17. A provision, when in compliance with federal law and regulation and approved by the Centers 104 for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid 105 program and may be provided by school divisions, regardless of whether the student receiving care has 106 an individualized education program or whether the health care service is included in a student's 107 108 individualized education program. Such services shall include those covered under the state plan for 109 medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) 110 benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for 111 payment of medical assistance for health care services provided through telemedicine services, as 112 defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for 113 providing telemedicine services; 114

18. A provision for payment of medical assistance services for liver, heart and lung transplantation 115 116 procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or 117 surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and 118 application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of 119 120 Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team 121

HB1323H3

or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy
has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is
not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and
restore a range of physical and social functioning in the activities of daily living;

126 19. A provision for payment of medical assistance for colorectal cancer screening, specifically 127 screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in 128 appropriate circumstances radiologic imaging, in accordance with the most recently published 129 recommendations established by the American College of Gastroenterology, in consultation with the 130 American Cancer Society, for the ages, family histories, and frequencies referenced in such 131 recommendations;

132

20. A provision for payment of medical assistance for custom ocular prostheses;

133 21. A provision for payment for medical assistance for infant hearing screenings and all necessary
134 audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the
135 United States Food and Drug Administration, and as recommended by the national Joint Committee on
136 Infant Hearing in its most current position statement addressing early hearing detection and intervention
137 programs. Such provision shall include payment for medical assistance for follow-up audiological
138 examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and
139 performed by a licensed audiologist to confirm the existence or absence of hearing loss;

140 22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer 141 Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer 142 when such women (i) have been screened for breast or cervical cancer under the Centers for Disease 143 Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under 144 Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including 145 treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under 146 creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise 147 eligible for medical assistance services under any mandatory categorically needy eligibility group; and 148 (v) have not attained age 65. This provision shall include an expedited eligibility determination for such 149 women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and
services delivery, of medical assistance services provided to medically indigent children pursuant to this
chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the
FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for
both programs;

155 24. A provision, when authorized by and in compliance with federal law, to establish a public-private 156 long-term care partnership program between the Commonwealth of Virginia and private insurance 157 companies that shall be established through the filing of an amendment to the state plan for medical 158 assistance services by the Department of Medical Assistance Services. The purpose of the program shall 159 be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for 160 such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first 161 162 source of benefits for the participant's long-term care. Components of the program, including the 163 treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with 164 federal law and applicable federal guidelines;

165 25. A provision for the payment of medical assistance for otherwise eligible pregnant women during
166 the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health
167 Insurance Program Reauthorization Act of 2009 (P.L. 111-3);

168 26. A provision for the payment of medical assistance for medically necessary health care services 169 provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or 170 whether the patient is accompanied by a health care provider at the time such services are provided. No 171 health care provider who provides health care services through telemedicine services shall be required to 172 use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is
located, including any medical care facility or office of a health care provider, the home of the patient,
the patient's place of employment, or any public or private primary or secondary school or
postsecondary institution of higher education at which the person to whom telemedicine services are
provided is located;

178 27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a
12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the
180 Department shall not impose any utilization controls or other forms of medical management limiting the
181 supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a
12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe,

183 dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time or (ii) 184 exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of 185 practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal 186 contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, 187 including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and 188

189 28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex 190 191 infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three 192 months following the date of such surgery; and (v) patients with a chronic health condition who have 193 had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" 194 195 means the use of digital technologies to collect medical and other forms of health data from patients in 196 one location and electronically transmit that information securely to health care providers in a different 197 location for analysis, interpretation, and recommendations, and management of the patient. "Remote 198 patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, 199 pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence 200 monitoring, and interactive videoconferencing with or without digital image upload. 201

B. In preparing the plan, the Board shall:

202 1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided 203 and that the health, safety, security, rights and welfare of patients are ensured. 204

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

205 3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the 206 provisions of this chapter.

207 4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations 208 pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social 209 services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact 210 analysis with local boards of social services prior to submission to the Registrar. The fiscal impact 211 analysis shall include the projected costs/savings to the local boards of social services to implement or 212 comply with such regulation and, where applicable, sources of potential funds to implement or comply 213 with such regulation.

214 5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in 215 accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities 216 With Deficiencies."

217 6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each 218 219 recipient of medical assistance services, and shall upon any changes in the required data elements set 220 forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective 221 information as may be required to electronically process a prescription claim.

222 C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for 223 medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, 224 regardless of any other provision of this chapter, such amendments to the state plan for medical 225 assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of 226 227 these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health 228 and Human Services.

229 In the event conforming amendments to the state plan for medical assistance services are adopted, the 230 Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 231 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the 232 Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or 233 regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the 234 regulations are necessitated by an emergency situation. Any such amendments that are in conflict with 235 the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular 236 session of the General Assembly unless enacted into law. 237

D. The Director of Medical Assistance Services is authorized to:

238 1. Administer such state plan and receive and expend federal funds therefor in accordance with 239 applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to 240 the performance of the Department's duties and the execution of its powers as provided by law.

241 2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other 242 health care providers where necessary to carry out the provisions of such state plan. Any such agreement 243 or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is 244 reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new

HB1323H3

245 agreement or contract. Such provider may also apply to the Director for reconsideration of the 246 agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement 247 248 or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or 249 pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider 250 as required by 42 C.F.R. § 1002.212.

251 4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement 252 or contract, with a provider who is or has been a principal in a professional or other corporation when 253 such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 254 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal 255 program pursuant to 42 C.F.R. Part 1002.

256 5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection 257 E of § 32.1-162.13. 258

For the purposes of this subsection, "provider" may refer to an individual or an entity.

259 E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider 260 pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. 261 § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of 262 263 the date of receipt of the notice.

264 The Director may consider aggravating and mitigating factors including the nature and extent of any 265 adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to 266 267 subsection D, the Director may determine the period of exclusion and may consider aggravating and 268 mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant 269 to 42 C.F.R. § 1002.215.

270 F. When the services provided for by such plan are services which a marriage and family therapist, 271 clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed 272 to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, 273 duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or 274 licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter 275 shall pay for covered services as provided in the state plan. The Board shall promulgate regulations 276 which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical 277 social workers, licensed professional counselors and licensed clinical nurse specialists at rates based 278 upon reasonable criteria, including the professional credentials required for licensure.

279 G. The Board shall prepare and submit to the Secretary of the United States Department of Health 280 and Human Services such amendments to the state plan for medical assistance services as may be 281 permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of 282 283 providing medical assistance under the plan to their parents. 284

H. The Department of Medical Assistance Services shall:

285 1. Include in its provider networks and all of its health maintenance organization contracts a 286 provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have 287 special needs and who are Medicaid eligible, including individuals who have been victims of child abuse 288 and neglect, for medically necessary assessment and treatment services, when such services are delivered 289 by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a 290 provider with comparable expertise, as determined by the Director.

291 2. Amend the Medallion II waiver and its implementing regulations to develop and implement an 292 exception, with procedural requirements, to mandatory enrollment for certain children between birth and 293 age three certified by the Department of Behavioral Health and Developmental Services as eligible for 294 services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

295 3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to 296 contractors and enrolled providers for the provision of health care services under Medicaid and the 297 Family Access to Medical Insurance Security Plan established under § 32.1-351.

298 4. Require any managed care organization with which the Department enters into an agreement for 299 the provision of medical assistance services to include in any contract between the managed care 300 organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or 301 a representative of the pharmacy benefits manager from conducting spread pricing with regards to the 302 managed care organization's managed care plans. For the purposes of this subdivision:

303 "Pharmacy benefits management" means the administration or management of prescription drug 304 benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management. 305

306 "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits 307 manager charges a managed care plan a contracted price for prescription drugs, and the contracted price 308 for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly 309 pays the pharmacist or pharmacy for pharmacist services.

310 I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible 311 recipients with special needs. The Board shall promulgate regulations regarding these special needs 312 patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board. 313

314 J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public 315 Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by 316 subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law 317 and regulation.

318 K. When services provided for by the plan described in subsection A are services related to initiation 319 of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy 320 technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide 321 reimbursement for such services.

322 § 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled 323 substances by pharmacists.

324 A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, 325 or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to 326 persons 18 years of age or older and persons authorized to consent pursuant to subsection E of 327 § 54.1-2969 with whom the pharmacist has a bona fide pharmacist-patient relationship and in accordance with a statewide protocol developed by the Board in collaboration with the Board of 328 329 Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in 330 331 § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist; 332

2. Epinephrine;

333 3. Injectable or self-administered hormonal contraceptives, provided the patient completes an 334 assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use; 335

4. Prenatal vitamins for which a prescription is required;

336 5. Dietary fluoride supplements, in accordance with recommendations of the American Dental 337 Association for prescribing of such supplements for persons whose drinking water has a fluoride content 338 below the concentration recommended by the U.S. Department of Health and Human Services;

339 6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the 340 341 patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to 342 purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other 343 supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control 344 and Prevention or that have a current emergency use authorization from the U.S. Food and Drug 345 346 Administration and vaccines for COVID-19; 347

8. Tuberculin purified protein derivative for tuberculosis testing; and

348 9. Controlled substances for the prevention of human immunodeficiency virus, including controlled 349 substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and 350 recommendations of the Centers for Disease Control and Prevention;

351 10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient 352 353 counseling:

354 11. Controlled substances or devices for the initiation of treatment of the following diseases or 355 conditions for which clinical decision making can be guided by a clinical test that is classified as 356 waived under the federal Clinical Laboratory Improvement Amendments of 1988: group A streptococcus 357 bacteria infection, influenza virus infection, and urinary tract infection; and 358

12. Tests for COVID-19 and other coronaviruses.

359 B. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, 360 or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board: 361

362 1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and 363 364

2. Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to 365 this section shall notify the patient's primary health care provider that the pharmacist has initiated 366 367 treatment with such drug or device or that such drug or device has been dispensed or administered to

HB1323H3

7 of 8

368 the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability 369 of notification to be sent to the patient's primary care provider by requiring use of electronic mail that 370 is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.). If the patient does not have a primary health care provider, the pharmacist shall 371 372 counsel the patient regarding the benefits of establishing a relationship with a primary health care 373 provider and, upon request, provide information regarding primary health care providers, including 374 federally qualified health centers, free clinics, or local health departments serving the area in which the 375 patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or 376 self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking 377 preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, 378 and (iii) pap smears.

379 C. D. A pharmacist who administers a vaccination pursuant to subdivision subdivisions A 7 and B 1 380 shall report such administration to the Virginia Immunization Information System in accordance with the 381 requirements of § 32.1-46.01.

382 E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled 383 paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the 384 patient, including questioning the patient for any known allergies, adverse reactions, contraindications, 385 or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or 386 administration.

387 F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled 388 paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, 389 as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the 390 applicable standard of care.

391 G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide 392 written notice to the minor's parent or guardian that the minor should visit a pediatrician annually. 393

§ 54.1-3321. Registration of pharmacy technicians.

394 A. No person shall perform the duties of a pharmacy technician without first being registered as a 395 pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, 396 the following tasks may be performed:

397 1. The entry of prescription information and drug history into a data system or other record keeping 398 system;

399 2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory; 400

401 4. The counting, measuring, or compounding of the drug to be dispensed;

402 5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

403 6. The stocking or loading of automated dispensing devices or other devices used in the dispensing **404** process;

405 7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there 406 is no change to the original prescription; and

407 8. Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same 408 physical location as the pharmacy technician, and consistent with the requirements of § 54.1-3303.1, 409 administration of the following drugs and devices to persons three years of age or older as set forth in 410 regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for 411 Disease Control and Prevention and vaccines for COVID-19; and

412 9. The performance of any other task restricted to pharmacy technicians by the Board's regulations. 413

B. To be registered as a pharmacy technician, a person shall submit:

414 1. An application and fee specified in regulations of the Board;

415 2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) 416 an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) 417 418 operated through a federal agency or branch of the military; and

419 3. Evidence that he has successfully passed a national certification examination administered by the 420 Pharmacy Technician Certification Board or the National Healthcareer Association.

421 C. The Board shall promulgate regulations establishing requirements for:

422 1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of 423 such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician 424 training program or (ii) passed a national certification examination required by the Board but did not 425 complete a Board-approved pharmacy technician training program;

426 2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as 427 a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification 428 examination required by the Board; and

429 3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy430 technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works
as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this
subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use
registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy.
The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with
a limited-use registration by paying the current renewal fee.

437 E. Any person registered as a pharmacy technician prior to the effective date of regulations
438 implementing the provisions of this section shall not be required to comply with the requirements of
439 subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described
in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining
practical experience required for completion of the training program, so long as such activities are
directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee
specified in regulations of the Board. Such registration shall only be valid while the person is enrolled
in a pharmacy technician training program described in subsection B and actively progressing toward
completion of such program. A registration card issued pursuant to this section shall be invalid and shall
be returned to the Board if such person fails to enroll in a pharmacy technician training program
described in subsection B.

450 H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A
451 when registered with the Board for the purpose of gaining the practical experience required to apply for
452 licensure as a pharmacist.

453 2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department 454 of Health, shall establish a statewide protocol for the initiation of treatment with and dispensing 455 and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2022, and the Board of Pharmacy shall 456 457 promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that 458 459 physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq., as 460 461 amended.

462 3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as 463 amended by this act, shall become effective upon the expiration of the provisions of the federal 464 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

465 Countermeasures Against COVID-19 related to the administration of COVID-19 vaccines to and 466 COVID-19 testing of minors.