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HOUSE BILL NO. 1323

Offered January 21, 2022

A BILL to amend and reenact §§ 32.1-325, 38.2-3408, and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

Patron—Orrock

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 38.2-3408, and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:

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

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

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial 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 value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

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 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 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 definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

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

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

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the 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 or Standards shall include any changes thereto within six months of the publication of such Guidelines 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 funds shall be used to perform, assist, encourage or make direct referrals for abortions;

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 cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

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 obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations;

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

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 necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of 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 the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

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

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal 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 specific antigen;

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

17. A provision, when in compliance with federal law and regulation and approved by the Centers 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 program and may be provided by school divisions;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and 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 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 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;

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

recommendations;

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

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

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

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for 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 source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines; and

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

B. In preparing the plan, the Board shall:

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

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

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

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

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

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 recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical

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 these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

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

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

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

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the 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 or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

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

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

6. (Expires January 1, 2020) Provide payments or transfers pursuant to § 457 of the Internal Revenue Code to the deferred compensation plan described in § 51.1-602 on behalf of an individual who is a dentist or an oral and maxillofacial surgeon providing services as an independent contractor pursuant to a Medicaid agreement or contract under this section. Notwithstanding the provisions of § 51.1-600, an "employee" for purposes of Chapter 6 (§ 51.1-600 et seq.) of Title 51.1 shall include an independent contractor as described in this subdivision.

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

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 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 the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any 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 subsection D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

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

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be

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 providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

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

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

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

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

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

K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide reimbursement for such service in an amount that is no less than the reimbursement amount for such service by a health care provider licensed by the Board of Medicine.

§ 38.2-3408. Policy providing for reimbursement for services that may be performed by certain practitioners other than physicians.

A. If an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor, optometrist, optician, professional counselor, psychologist, clinical social worker, podiatrist, physical therapist, chiropodist, clinical nurse specialist, audiologist, speech pathologist, certified nurse midwife or other nurse practitioner, marriage and family therapist, or licensed acupuncturist, reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner.

B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the policy shall not be denied because the service is rendered by the licensed pharmacist, provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, (ii) the service is for the administration of vaccines for immunization, or (iii) the service is provided in accordance with § 54.1-3303.1. *If the service is for the initiation of treatment with or dispensing or administration of vaccines by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, such policy shall provide reimbursement in an amount that is no less than the reimbursement amount for such service by a health care provider licensed by the Board of Medicine.*

C. This section shall not apply to Medicaid, or any state fund.

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

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of 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 § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

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 patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

~~7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;~~

~~8.~~ Tuberculin purified protein derivative for tuberculosis testing; and

~~9.~~ *8.* Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

C. *Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer to persons three years of age or older in accordance with a statewide protocol developed by the Board in consultation with the Board of Medicine and the Department of Health and set forth in regulations of the Board vaccines authorized by the U.S. Food and Drug Administration, including vaccines authorized for emergency use in response to a public health emergency, or may cause such vaccines to be administered by a pharmacy technician or pharmacy intern under the direct supervision of the pharmacist.* A pharmacist who administers a vaccination pursuant to ~~subdivision A 7~~ *this subsection* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.