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HOUSE BILL NO. 367

Offered January 8, 2020

Prefiled January 2, 2020

A BILL to amend and reenact § 32.1-325 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 5 of Title 32.1 an article numbered 8, consisting of a section numbered 32.1-162.15:2, relating to donated human breast milk; payment of medical assistance.

Patron—Carroll Foy

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-325 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Chapter 5 of Title 32.1 an article numbered 8, consisting of a section numbered 32.1-162.15:2, as follows:

Article 8.

Licensing of Human Breast Milk Banks.

§ 32.1-162.15:2. Human breast milk banks; license required; renewal; standards.

A. No person shall establish or operate a human breast milk bank without first obtaining a license issued by the Commissioner.

B. The Commissioner shall establish criteria for the licensure of human breast milk banks, which shall include (i) a process for licensure and renewal of a license as a human breast milk bank; (ii) appropriate fees for licensure and renewal of a license as a human breast milk bank; (iii) standards and requirements for human breast milk banks to protect the health and safety of the public and ensure the quality of donated human breast milk and human breast milk derived products; (iv) provisions for inspections of human breast milk banks; and (v) provisions for revocation or denial of a license to operate a human breast milk bank.

C. Requirements for human breast milk banks developed pursuant to clause (iii) of subsection B shall (i) provide for the testing of all donated human breast milk and human breast milk derived products for the presence of nicotine, tetrahydrocannabinol, opioids and opiates, or any metabolite thereof, and any other substances that the Department may deem appropriate, and (ii) prohibit the sale, distribution, processing, or donation of any human breast milk and human breast milk derived products that contain such substances.

§ 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

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59 assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and
60 lot used as the principal residence and all contiguous property essential to the operation of the home
61 regardless of value;

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

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

67 6. A provision for payment of medical assistance on behalf of pregnant women which provides for
68 payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most
69 current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American
70 Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards
71 for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and
72 Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the
73 children which are within the time periods recommended by the attending physicians in accordance with
74 and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines
75 or Standards shall include any changes thereto within six months of the publication of such Guidelines
76 or Standards or any official amendment thereto;

77 7. A provision for the payment for family planning services on behalf of women who were
78 Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such
79 family planning services shall begin with delivery and continue for a period of 24 months, if the woman
80 continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the
81 purposes of this section, family planning services shall not cover payment for abortion services and no
82 funds shall be used to perform, assist, encourage or make direct referrals for abortions;

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

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

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

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

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

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

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

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

118 16. A provision for payment of medical assistance for low-dose screening mammograms for
119 determining the presence of occult breast cancer. Such coverage shall make available one screening
120 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;

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); and

182 26. A provision for the payment of medical assistance for medically necessary health care services
183 provided through telemedicine services; and

184 27. *A provision for the payment of medical assistance for pasteurized donated human breast milk*
185 *from a human breast milk bank licensed pursuant to § 32.1-162.15:2 in accordance with a written order*
186 *of a licensed health care provider for a child who is under six months of age and (i) is medically or*
187 *physically unable to receive maternal breast milk or to participate in breastfeeding or whose mother is*
188 *medically or physically unable to produce maternal breast milk in sufficient quantities or to participate*
189 *in breast feeding despite lactation support; (ii) has a body weight that is below a healthy level, as*
190 *determined by a health care provider; or (iii) has a congenital or acquired condition that places the*
191 *infant at a high risk for development of necrotizing enterocolitis or that may benefit from the use of*
192 *pasteurized donated human breast milk, as determined by a health care provider. For the purposes of*
193 *this subdivision, "pasteurized donated human breast milk" shall include human breast milk-based*
194 *fortifiers if such human breast milk-based fortifiers are included in a written order for pasteurized*
195 *donated human breast milk issued by a licensed health care provider.*

196 B. In preparing the plan, the Board shall:

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

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

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

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

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

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

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

224 In the event conforming amendments to the state plan for medical assistance services are adopted, the
225 Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter
226 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the
227 Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or
228 regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the
229 regulations are necessitated by an emergency situation. Any such amendments that are in conflict with
230 the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular
231 session of the General Assembly unless enacted into law.

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

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

236 2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other
237 health care providers where necessary to carry out the provisions of such state plan. Any such agreement
238 or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is
239 reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new
240 agreement or contract. Such provider may also apply to the Director for reconsideration of the
241 agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

242 3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement
243 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.

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.