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**SENATE BILL NO. 1186**

AMENDMENT IN THE NATURE OF A SUBSTITUTE  
 (Proposed by the Senate Committee on Education and Health  
 on January 23, 2025)

(Patron Prior to Substitute—Senator Carroll Foy)

*A BILL to amend and reenact §§ 2.2-2818, 32.1-325, and 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 5 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-162.15:12 through 32.1-162.15:22, and by adding a section numbered 38.2-3418.22, relating to donor human milk banks; health insurance; coverage for donor human milk; penalty.*

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 2.2-2818, 32.1-325, and 38.2-4319 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 5 of Title 32.1 an article numbered 9, consisting of sections numbered 32.1-162.15:12 through 32.1-162.15:22, and by adding a section numbered 38.2-3418.22 as follows:**

**§ 2.2-2818. Health and related insurance for state employees.**

A. The Department of Human Resource Management shall establish a plan, subject to the approval of the Governor, for providing health insurance coverage, including chiropractic treatment, hospitalization, medical, surgical, and major medical coverage, for state employees and retired state employees with the Commonwealth paying the cost thereof to the extent of the coverage included in such plan. The same plan shall be offered to all part-time state employees, but the total cost shall be paid by such part-time employees. The Department of Human Resource Management shall administer this section. The plan chosen shall provide means whereby coverage for the families or dependents of state employees may be purchased. Except for part-time employees, the Commonwealth may pay all or a portion of the cost thereof, and for such portion as the Commonwealth does not pay, the employee, including a part-time employee, may purchase the coverage by paying the additional cost over the cost of coverage for an employee.

Such contribution shall be financed through appropriations provided by law.

B. The plan shall:

1. Include coverage 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 and may be limited to a benefit of \$50 per mammogram subject to such dollar limits, deductibles, and coinsurance factors as are no less favorable than for physical illness generally.

The term "mammogram" shall mean 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.

In order to be considered a screening mammogram for which coverage shall be made available under this section:

a. The mammogram shall be (i) ordered by a health care practitioner acting within the scope of his licensure and, in the case of an enrollee of a health maintenance organization, by the health maintenance organization provider; (ii) performed by a registered technologist; (iii) interpreted by a qualified radiologist; and (iv) performed under the direction of a person licensed to practice medicine and surgery and certified by the American Board of Radiology or an equivalent examining body. A copy of the mammogram report shall be sent or delivered to the health care practitioner who ordered it;

b. The equipment used to perform the mammogram shall meet the standards set forth by the Virginia Department of Health in its radiation protection regulations; and

c. The mammography film shall be retained by the radiologic facility performing the examination in accordance with the American College of Radiology guidelines or state law.

2. Include coverage for postpartum services providing inpatient care and a home visit or visits that shall be 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. Such coverage shall be provided incorporating any changes in such Guidelines or Standards within six months of the publication of such Guidelines or Standards or any official amendment thereto.

3. Include an appeals process for resolution of complaints that shall provide reasonable procedures for the resolution of such complaints and shall be published and disseminated to all covered state employees. The appeals process shall be compliant with federal rules and regulations governing nonfederal, self-insured governmental health plans. The appeals process shall include a separate expedited emergency appeals

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60 procedure that shall provide resolution within time frames established by federal law. For appeals involving  
61 adverse decisions as defined in § 32.1-137.7, the Department shall contract with one or more independent  
62 review organizations to review such decisions. Independent review organizations are entities that conduct  
63 independent external review of adverse benefit determinations. The Department shall adopt regulations to  
64 assure that the independent review organization conducting the reviews has adequate standards, credentials  
65 and experience for such review. The independent review organization shall examine the final denial of claims  
66 to determine whether the decision is objective, clinically valid, and compatible with established principles of  
67 health care. The decision of the independent review organization shall (i) be in writing, (ii) contain findings  
68 of fact as to the material issues in the case and the basis for those findings, and (iii) be final and binding if  
69 consistent with law and policy.

70 Prior to assigning an appeal to an independent review organization, the Department shall verify that the  
71 independent review organization conducting the review of a denial of claims has no relationship or  
72 association with (i) the covered person or the covered person's authorized representative; (ii) the treating  
73 health care provider, or any of its employees or affiliates; (iii) the medical care facility at which the covered  
74 service would be provided, or any of its employees or affiliates; or (iv) the development or manufacture of  
75 the drug, device, procedure, or other therapy that is the subject of the final denial of a claim. The independent  
76 review organization shall not be a subsidiary of, nor owned or controlled by, a health plan, a trade association  
77 of health plans, or a professional association of health care providers. There shall be no liability on the part of  
78 and no cause of action shall arise against any officer or employee of an independent review organization for  
79 any actions taken or not taken or statements made by such officer or employee in good faith in the  
80 performance of his powers and duties.

81 4. Include coverage for early intervention services. For purposes of this section, "early intervention  
82 services" means medically necessary speech and language therapy, occupational therapy, physical therapy  
83 and assistive technology services and devices for dependents from birth to age three who are certified by the  
84 Department of Behavioral Health and Developmental Services as eligible for services under Part H of the  
85 Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.). Medically necessary early intervention  
86 services for the population certified by the Department of Behavioral Health and Developmental Services  
87 shall mean those services designed to help an individual attain or retain the capability to function age-  
88 appropriately within his environment, and shall include services that enhance functional ability without  
89 effecting a cure.

90 For persons previously covered under the plan, there shall be no denial of coverage due to the existence of  
91 a preexisting condition. The cost of early intervention services shall not be applied to any contractual  
92 provision limiting the total amount of coverage paid by the insurer to or on behalf of the insured during the  
93 insured's lifetime.

94 5. Include coverage for prescription drugs and devices approved by the United States Food and Drug  
95 Administration for use as contraceptives.

96 6. Not deny coverage for any drug approved by the United States Food and Drug Administration for use  
97 in the treatment of cancer on the basis that the drug has not been approved by the United States Food and  
98 Drug Administration for the treatment of the specific type of cancer for which the drug has been prescribed, if  
99 the drug has been recognized as safe and effective for treatment of that specific type of cancer in one of the  
100 standard reference compendia.

101 7. Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has been  
102 approved by the United States Food and Drug Administration for at least one indication and the drug is  
103 recognized for treatment of the covered indication in one of the standard reference compendia or in  
104 substantially accepted peer-reviewed medical literature.

105 8. Include coverage for equipment, supplies, and outpatient self-management training and education,  
106 including medical nutrition therapy, for the treatment of insulin-dependent diabetes, insulin-using diabetes,  
107 gestational diabetes, and noninsulin-using diabetes if prescribed by a health care professional legally  
108 authorized to prescribe such items under law. To qualify for coverage under this subdivision, diabetes  
109 outpatient self-management training and education shall be provided by a certified, registered, or licensed  
110 health care professional.

111 9. Include coverage for reconstructive breast surgery. For purposes of this section, "reconstructive breast  
112 surgery" means surgery performed on and after July 1, 1998, (i) coincident with a mastectomy performed for  
113 breast cancer or (ii) following a mastectomy performed for breast cancer to reestablish symmetry between the  
114 two breasts. For persons previously covered under the plan, there shall be no denial of coverage due to  
115 preexisting conditions.

116 10. Include coverage for annual pap smears, including coverage, on and after July 1, 1999, for annual  
117 testing performed by any FDA-approved gynecologic cytology screening technologies.

118 11. Include coverage providing a minimum stay in the hospital of not less than 48 hours for a patient  
119 following a radical or modified radical mastectomy and 24 hours of inpatient care following a total  
120 mastectomy or a partial mastectomy with lymph node dissection for treatment of breast cancer. Nothing in

121 this subdivision shall be construed as requiring the provision of inpatient coverage where the attending  
 122 physician in consultation with the patient determines that a shorter period of hospital stay is appropriate.

123 12. Include coverage (i) to persons age 50 and over and (ii) to persons age 40 and over who are at high  
 124 risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society,  
 125 for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American  
 126 Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood  
 127 sample to determine the level of prostate specific antigen.

128 13. Permit any individual covered under the plan direct access to the health care services of a participating  
 129 specialist (i) authorized to provide services under the plan and (ii) selected by the covered individual. The  
 130 plan shall have a procedure by which an individual who has an ongoing special condition may, after  
 131 consultation with the primary care physician, receive a referral to a specialist for such condition who shall be  
 132 responsible for and capable of providing and coordinating the individual's primary and specialty care related  
 133 to the initial specialty care referral. If such an individual's care would most appropriately be coordinated by  
 134 such a specialist, the plan shall refer the individual to a specialist. For the purposes of this subdivision,  
 135 "special condition" means a condition or disease that is (i) life-threatening, degenerative, or disabling and (ii)  
 136 requires specialized medical care over a prolonged period of time. Within the treatment period authorized by  
 137 the referral, such specialist shall be permitted to treat the individual without a further referral from the  
 138 individual's primary care provider and may authorize such referrals, procedures, tests, and other medical  
 139 services related to the initial referral as the individual's primary care provider would otherwise be permitted  
 140 to provide or authorize. The plan shall have a procedure by which an individual who has an ongoing special  
 141 condition that requires ongoing care from a specialist may receive a standing referral to such specialist for the  
 142 treatment of the special condition. If the primary care provider, in consultation with the plan and the  
 143 specialist, if any, determines that such a standing referral is appropriate, the plan or issuer shall make such a  
 144 referral to a specialist. Nothing contained herein shall prohibit the plan from requiring a participating  
 145 specialist to provide written notification to the covered individual's primary care physician of any visit to  
 146 such specialist. Such notification may include a description of the health care services rendered at the time of  
 147 the visit.

148 14. Include provisions allowing employees to continue receiving health care services for a period of up to  
 149 90 days from the date of the primary care physician's notice of termination from any of the plan's provider  
 150 panels. The plan shall notify any provider at least 90 days prior to the date of termination of the provider,  
 151 except when the provider is terminated for cause.

152 For a period of at least 90 days from the date of the notice of a provider's termination from any of the  
 153 plan's provider panels, except when a provider is terminated for cause, a provider shall be permitted by the  
 154 plan to render health care services to any of the covered employees who (i) were in an active course of  
 155 treatment from the provider prior to the notice of termination and (ii) request to continue receiving health care  
 156 services from the provider.

157 Notwithstanding the provisions of this subdivision, any provider shall be permitted by the plan to continue  
 158 rendering health services to any covered employee who has entered the second trimester of pregnancy at the  
 159 time of the provider's termination of participation, except when a provider is terminated for cause. Such  
 160 treatment shall, at the covered employee's option, continue through the provision of postpartum care directly  
 161 related to the delivery.

162 Notwithstanding the provisions of this subdivision, any provider shall be permitted to continue rendering  
 163 health services to any covered employee who is determined to be terminally ill (as defined under §  
 164 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, except  
 165 when a provider is terminated for cause. Such treatment shall, at the covered employee's option, continue for  
 166 the remainder of the employee's life for care directly related to the treatment of the terminal illness.

167 A provider who continues to render health care services pursuant to this subdivision shall be reimbursed  
 168 in accordance with the carrier's agreement with such provider existing immediately before the provider's  
 169 termination of participation.

170 15. Include coverage for patient costs incurred during participation in clinical trials for treatment studies  
 171 on cancer, including ovarian cancer trials.

172 The reimbursement for patient costs incurred during participation in clinical trials for treatment studies on  
 173 cancer shall be determined in the same manner as reimbursement is determined for other medical and surgical  
 174 procedures. Such coverage shall have durational limits, dollar limits, deductibles, copayments, and  
 175 coinsurance factors that are no less favorable than for physical illness generally.

176 For purposes of this subdivision:

177 "Cooperative group" means a formal network of facilities that collaborate on research projects and have  
 178 an established NIH-approved peer review program operating within the group. "Cooperative group" includes  
 179 (i) the National Cancer Institute Clinical Cooperative Group and (ii) the National Cancer Institute  
 180 Community Clinical Oncology Program.

181 "FDA" means the Federal Food and Drug Administration.

182 "Multiple project assurance contract" means a contract between an institution and the federal Department

183 of Health and Human Services that defines the relationship of the institution to the federal Department of  
184 Health and Human Services and sets out the responsibilities of the institution and the procedures that will be  
185 used by the institution to protect human subjects.

186 "NCI" means the National Cancer Institute.

187 "NIH" means the National Institutes of Health.

188 "Patient" means a person covered under the plan established pursuant to this section.

189 "Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the  
190 treatment being provided to a patient for purposes of a clinical trial. "Patient cost" does not include (i) the  
191 cost of nonhealth care services that a patient may be required to receive as a result of the treatment being  
192 provided for purposes of a clinical trial, (ii) costs associated with managing the research associated with the  
193 clinical trial, or (iii) the cost of the investigational drug or device.

194 Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided  
195 if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such treatment may,  
196 however, be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

197 The treatment described in the previous paragraph shall be provided by a clinical trial approved by:

198 a. The National Cancer Institute;

199 b. An NCI cooperative group or an NCI center;

200 c. The FDA in the form of an investigational new drug application;

201 d. The federal Department of Veterans Affairs; or

202 e. An institutional review board of an institution in the Commonwealth that has a multiple project  
203 assurance contract approved by the Office of Protection from Research Risks of the NCI.

204 The facility and personnel providing the treatment shall be capable of doing so by virtue of their  
205 experience, training, and expertise.

206 Coverage under this subdivision shall apply only if:

207 (1) There is no clearly superior, noninvestigational treatment alternative;

208 (2) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at  
209 least as effective as the noninvestigational alternative; and

210 (3) The patient and the physician or health care provider who provides services to the patient under the  
211 plan conclude that the patient's participation in the clinical trial would be appropriate, pursuant to procedures  
212 established by the plan.

213 16. Include coverage providing a minimum stay in the hospital of not less than 23 hours for a covered  
214 employee following a laparoscopy-assisted vaginal hysterectomy and 48 hours for a covered employee  
215 following a vaginal hysterectomy, as outlined in Milliman & Robertson's nationally recognized guidelines.  
216 Nothing in this subdivision shall be construed as requiring the provision of the total hours referenced when  
217 the attending physician, in consultation with the covered employee, determines that a shorter hospital stay is  
218 appropriate.

219 17. Include coverage for biologically based mental illness.

220 For purposes of this subdivision, a "biologically based mental illness" is any mental or nervous condition  
221 caused by a biological disorder of the brain that results in a clinically significant syndrome that substantially  
222 limits the person's functioning; specifically, the following diagnoses are defined as biologically based mental  
223 illness as they apply to adults and children: schizophrenia, schizoaffective disorder, bipolar disorder, major  
224 depressive disorder, panic disorder, obsessive-compulsive disorder, attention deficit hyperactivity disorder,  
225 autism, and drug and alcoholism addiction.

226 Coverage for biologically based mental illnesses shall neither be different nor separate from coverage for  
227 any other illness, condition, or disorder for purposes of determining deductibles, benefit year or lifetime  
228 durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment limits, copayment and  
229 coinsurance factors, and benefit year maximum for deductibles and copayment and coinsurance factors.

230 Nothing shall preclude the undertaking of usual and customary procedures to determine the  
231 appropriateness of, and medical necessity for, treatment of biologically based mental illnesses under this  
232 option, provided that all such appropriateness and medical necessity determinations are made in the same  
233 manner as those determinations made for the treatment of any other illness, condition, or disorder covered by  
234 such policy or contract.

235 18. Offer and make available coverage for the treatment of morbid obesity through gastric bypass surgery  
236 or such other methods as may be recognized by the National Institutes of Health as effective for the long-term  
237 reversal of morbid obesity. Such coverage shall have durational limits, dollar limits, deductibles, copayments,  
238 and coinsurance factors that are no less favorable than for physical illness generally. Access to surgery for  
239 morbid obesity shall not be restricted based upon dietary or any other criteria not approved by the National  
240 Institutes of Health. For purposes of this subdivision, "morbid obesity" means (i) a weight that is at least 100  
241 pounds over or twice the ideal weight for frame, age, height, and gender as specified in the 1983 Metropolitan  
242 Life Insurance tables, (ii) a body mass index (BMI) equal to or greater than 35 kilograms per meter squared  
243 with comorbidity or coexisting medical conditions such as hypertension, cardiopulmonary conditions, sleep

244 apnea, or diabetes, or (iii) a BMI of 40 kilograms per meter squared without such comorbidity. As used  
 245 herein, "BMI" equals weight in kilograms divided by height in meters squared.

246 19. Include coverage for colorectal cancer screening, specifically screening with an annual fecal occult  
 247 blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in  
 248 accordance with the most recently published recommendations established by the American College of  
 249 Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and  
 250 frequencies referenced in such recommendations. The coverage for colorectal cancer screening shall not be  
 251 more restrictive than or separate from coverage provided for any other illness, condition, or disorder for  
 252 purposes of determining deductibles, benefit year or lifetime durational limits, benefit year or lifetime dollar  
 253 limits, lifetime episodes or treatment limits, copayment and coinsurance factors, and benefit year maximum  
 254 for deductibles and copayments and coinsurance factors.

255 20. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or  
 256 other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each employee  
 257 provided coverage pursuant to this section, and shall upon any changes in the required data elements set forth  
 258 in subsection A of § 38.2-3407.4:2, either reissue the card or provide employees covered under the plan such  
 259 corrective information as may be required to electronically process a prescription claim.

260 21. Include coverage for infant hearing screenings and all necessary audiological examinations provided  
 261 pursuant to § 32.1-64.1 using any technology approved by the United States Food and Drug Administration,  
 262 and as recommended by the national Joint Committee on Infant Hearing in its most current position statement  
 263 addressing early hearing detection and intervention programs. Such coverage shall include follow-up  
 264 audiological examinations as recommended by a physician, a physician assistant, an advanced practice  
 265 registered nurse, or an audiologist and performed by a licensed audiologist to confirm the existence or  
 266 absence of hearing loss.

267 22. *Include inpatient and outpatient coverage for the provision of pasteurized donor human milk and*  
 268 *human milk-derived products for an infant younger than 12 months corrected age, as defined in §*  
 269 *32.1-162.15:12, (i) who lacks sufficient access to his mother's maternal breast milk, (ii) for whom a licensed*  
 270 *health care provider has issued a written order for the provision of such milk or milk-derived product, and*  
 271 *(iii) who meets one of the following medical criteria:*

- 272 a. Birth weight less than or equal to 1,500 grams;
- 273 b. Birth less than or equal to 34 weeks' gestation;
- 274 c. A diagnosis of:

275 (1) *A health condition that places the infant at a high risk for the development of necrotizing enterocolitis,*  
 276 *bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity;*

277 (2) *An immunologic deficiency or the need for an organ or bone marrow transplant; or*

278 (3) *Any other serious congenital or acquired condition for which the use of pasteurized donor human milk*  
 279 *is medically necessary and supports the treatment and recovery of the infant as determined by the*  
 280 *Department.*

281 *Pasteurized donor human milk obtained pursuant to this subdivision shall be obtained from a donor*  
 282 *human milk bank that is licensed by the Department of Health pursuant to Article 9 (§ 32.1-162.15:12 et seq.)*  
 283 *of Chapter 5 of Title 32.1.*

284 Notwithstanding any provision of this section to the contrary, every plan established in accordance with  
 285 this section shall comply with the provisions of § 2.2-2818.2.

286 C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such  
 287 funds as shall be appropriated by law. Appropriations, premiums, and other payments shall be deposited in  
 288 the employee health insurance fund, from which payments for claims, premiums, cost containment programs,  
 289 and administrative expenses shall be withdrawn from time to time. The funds of the health insurance fund  
 290 shall be deemed separate and independent trust funds, shall be segregated from all other funds of the  
 291 Commonwealth, and shall be invested and administered solely in the interests of the employees and their  
 292 beneficiaries. Neither the General Assembly nor any public officer, employee, or agency shall use or  
 293 authorize the use of such trust funds for any purpose other than as provided in law for benefits, refunds, and  
 294 administrative expenses, including but not limited to legislative oversight of the health insurance fund.

295 D. For the purposes of this section:

296 "Peer-reviewed medical literature" means a scientific study published only after having been critically  
 297 reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal that has  
 298 been determined by the International Committee of Medical Journal Editors to have met the Uniform  
 299 Requirements for Manuscripts submitted to biomedical journals. "Peer-reviewed medical literature" does not  
 300 include publications or supplements to publications that are sponsored to a significant extent by a  
 301 pharmaceutical manufacturing company or health carrier.

302 "Standard reference compendia" means:

- 303 1. American Hospital Formulary Service — Drug Information;
- 304 2. National Comprehensive Cancer Network's Drugs & Biologics Compendium; or
- 305 3. Elsevier Gold Standard's Clinical Pharmacology.

306 "State employee" means state employee as defined in § 51.1-124.3; employee as defined in § 51.1-201;  
307 the Governor, Lieutenant Governor and Attorney General; judge as defined in § 51.1-301 and judges, clerks,  
308 and deputy clerks of regional juvenile and domestic relations, county juvenile and domestic relations, and  
309 district courts of the Commonwealth; interns and residents employed by the School of Medicine and Hospital  
310 of the University of Virginia, and interns, residents, and employees of the Virginia Commonwealth  
311 University Health System Authority as provided in § 23.1-2415; and employees of the Virginia Alcoholic  
312 Beverage Control Authority as provided in § 4.1-101.05.

313 E. Provisions shall be made for retired employees to obtain coverage under the above plan, including, as  
314 an option, coverage for vision and dental care. The Commonwealth may, but shall not be obligated to, pay all  
315 or any portion of the cost thereof.

316 F. Any self-insured group health insurance plan established by the Department of Human Resource  
317 Management that utilizes a network of preferred providers shall not exclude any physician solely on the basis  
318 of a reprimand or censure from the Board of Medicine, so long as the physician otherwise meets the plan  
319 criteria established by the Department.

320 G. The plan shall include, in each planning district, at least two health coverage options, each sponsored  
321 by unrelated entities. No later than July 1, 2006, one of the health coverage options to be available in each  
322 planning district shall be a high deductible health plan that would qualify for a health savings account  
323 pursuant to § 223 of the Internal Revenue Code of 1986, as amended.

324 In each planning district that does not have an available health coverage alternative, the Department shall  
325 voluntarily enter into negotiations at any time with any health coverage provider who seeks to provide  
326 coverage under the plan.

327 This subsection shall not apply to any state agency authorized by the Department to establish and  
328 administer its own health insurance coverage plan separate from the plan established by the Department.

329 H. Any self-insured group health insurance plan established by the Department of Human Resource  
330 Management that includes coverage for prescription drugs on an outpatient basis may apply a formulary to  
331 the prescription drug benefits provided by the plan if the formulary is developed, reviewed at least annually,  
332 and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics  
333 committee, a majority of whose members are actively practicing licensed (i) pharmacists, (ii) physicians, and  
334 (iii) other health care providers.

335 If the plan maintains one or more drug formularies, the plan shall establish a process to allow a person to  
336 obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the plan, a  
337 specific, medically necessary nonformulary prescription drug if, after reasonable investigation and  
338 consultation with the prescriber, the formulary drug is determined to be an inappropriate therapy for the  
339 medical condition of the person. The plan shall act on such requests within one business day of receipt of the  
340 request.

341 Any plan established in accordance with this section shall be authorized to provide for the selection of a  
342 single mail order pharmacy provider as the exclusive provider of pharmacy services that are delivered to the  
343 covered person's address by mail, common carrier, or delivery service. As used in this subsection, "mail order  
344 pharmacy provider" means a pharmacy permitted to conduct business in the Commonwealth whose primary  
345 business is to dispense a prescription drug or device under a prescriptive drug order and to deliver the drug or  
346 device to a patient primarily by mail, common carrier, or delivery service.

347 I. Any plan established in accordance with this section requiring preauthorization prior to rendering  
348 medical treatment shall have personnel available to provide authorization at all times when such  
349 preauthorization is required.

350 J. Any plan established in accordance with this section shall provide to all covered employees written  
351 notice of any benefit reductions during the contract period at least 30 days before such reductions become  
352 effective.

353 K. No contract between a provider and any plan established in accordance with this section shall include  
354 provisions that require a health care provider or health care provider group to deny covered services that such  
355 provider or group knows to be medically necessary and appropriate that are provided with respect to a  
356 covered employee with similar medical conditions.

357 L. The Department of Human Resource Management shall appoint an Ombudsman to promote and protect  
358 the interests of covered employees under any state employee's health plan.

359 The Ombudsman shall:

360 1. Assist covered employees in understanding their rights and the processes available to them according to  
361 their state health plan.

362 2. Answer inquiries from covered employees by telephone and electronic mail.

363 3. Provide to covered employees information concerning the state health plans.

364 4. Develop information on the types of health plans available, including benefits and complaint  
365 procedures and appeals.

366 5. Make available, either separately or through an existing Internet web site utilized by the Department of

367 Human Resource Management, information as set forth in subdivision 4 and such additional information as  
 368 he deems appropriate.

369 6. Maintain data on inquiries received, the types of assistance requested, any actions taken and the  
 370 disposition of each such matter.

371 7. Upon request, assist covered employees in using the procedures and processes available to them from  
 372 their health plan, including all appeal procedures. Such assistance may require the review of health care  
 373 records of a covered employee, which shall be done only in accordance with the federal Health Insurance  
 374 Portability and Accountability Act privacy rules. The confidentiality of any such medical records shall be  
 375 maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

376 8. Ensure that covered employees have access to the services provided by the Ombudsman and that the  
 377 covered employees receive timely responses from the Ombudsman or his representatives to the inquiries.

378 9. Report annually on his activities to the standing committees of the General Assembly having  
 379 jurisdiction over insurance and over health and the Joint Commission on Health Care by December 1 of each  
 380 year.

381 M. The plan established in accordance with this section shall not refuse to accept or make reimbursement  
 382 pursuant to an assignment of benefits made to a dentist or oral surgeon by a covered employee.

383 For purposes of this subsection, "assignment of benefits" means the transfer of dental care coverage  
 384 reimbursement benefits or other rights under the plan. The assignment of benefits shall not be effective until  
 385 the covered employee notifies the plan in writing of the assignment.

386 N. Beginning July 1, 2006, any plan established pursuant to this section shall provide for an identification  
 387 number, which shall be assigned to the covered employee and shall not be the same as the employee's social  
 388 security number.

389 O. Any group health insurance plan established by the Department of Human Resource Management that  
 390 contains a coordination of benefits provision shall provide written notification to any eligible employee as a  
 391 prominent part of its enrollment materials that if such eligible employee is covered under another group  
 392 accident and sickness insurance policy, group accident and sickness subscription contract, or group health  
 393 care plan for health care services, that insurance policy, subscription contract, or health care plan may have  
 394 primary responsibility for the covered expenses of other family members enrolled with the eligible employee.  
 395 Such written notification shall describe generally the conditions upon which the other coverage would be  
 396 primary for dependent children enrolled under the eligible employee's coverage and the method by which the  
 397 eligible enrollee may verify from the plan that coverage would have primary responsibility for the covered  
 398 expenses of each family member.

399 P. Any plan established by the Department of Human Resource Management pursuant to this section shall  
 400 provide that coverage under such plan for family members enrolled under a participating state employee's  
 401 coverage shall continue for a period of at least 30 days following the death of such state employee.

402 Q. The plan established in accordance with this section that follows a policy of sending its payment to the  
 403 covered employee or covered family member for a claim for services received from a nonparticipating  
 404 physician or osteopath shall (i) include language in the member handbook that notifies the covered employee  
 405 of the responsibility to apply the plan payment to the claim from such nonparticipating provider, (ii) include  
 406 this language with any such payment sent to the covered employee or covered family member, and (iii)  
 407 include the name and any last known address of the nonparticipating provider on the explanation of benefits  
 408 statement.

409 R. The plan established by the Department of Human Resource Management pursuant to this section shall  
 410 provide that coverage under such plan for an incapacitated child enrolled under a participating state  
 411 employee's coverage shall be valid without regard to whether such child lives with the covered employee as a  
 412 member of the employee's household so long as the child is dependent upon the employee for more than half  
 413 of the child's financial support and the child is receiving residential support services.

414 For purposes of this subsection, "incapacitated child" means an adult child who is incapacitated due to a  
 415 physical or mental health condition that existed prior to the termination of coverage due to such child  
 416 attaining the limiting age under the plan for eligible children dependents.

417 S. The Department of Human Resource Management shall report annually, by November 30 of each year,  
 418 on cost and utilization information for each of the mandated benefits set forth in subsection B, including any  
 419 mandated benefit made applicable, pursuant to subdivision B 22, to any plan established pursuant to this  
 420 section. The report shall be in the same detail and form as required of reports submitted pursuant to §  
 421 38.2-3419.1, with such additional information as is required to determine the financial impact, including the  
 422 costs and benefits, of the particular mandated benefit.

423 *Article 9.*

424 *Donor Human Milk Banks.*

425 **§ 32.1-162.15:12. Definitions.**

426 *For the purposes of this article, unless the context requires a different meaning:*

427 *"Collect" means to obtain human breast milk from a donor for the purpose of selling or distributing*

428 pasteurized donor human milk or human milk-derived products to children other than the donor's own child.

429 "Corrected age" means the age of a premature infant minus the number of weeks or months the infant was  
430 born prematurely.

431 "Donor human milk bank" means an entity that, for the purposes of donor human milk banking, (i)  
432 collects from a donor and pasteurizes or stores donor human milk and human milk-derived products for  
433 children other than the donor's own child or (ii) sells or distributes such milk or products to children other  
434 than the donor's own child based on a health care provider's order or prescription. "Donor human milk bank  
435 " does not include any person who expresses human milk and stores such human milk at her residence for the  
436 purpose of donating such milk to (a) a donor human milk bank licensed pursuant to this article, (b) to the  
437 parent of a child other than such person's own child, or (c) a cooperative that shares human breast milk.

438 "Express" means removal of human breast milk from the breast other than when a baby is nursing, includ  
439 ing hand expression and the use of manual or electric pump machines.

440 "Fund" means the Donor Human Milk Bank Fund established in § 32.1-162.15:14.

441 "Purchaser" means any person who buys or is supplied pasteurized donor human milk by a licensed  
442 donor human milk bank.

443 "Satellite milk depot" means a human donor milk collection site affiliated with a licensed donor human  
444 milk bank where a donor may drop off donated human milk.

445 "Store" means holding or freezing donor human milk in connection with collection or pasteurization prior  
446 to sale or distribution.

447 **§ 32.1-162.15:13. Donor human milk banks; license required; penalty.**

448 A. No person shall own, establish, conduct, maintain, manage, or operate a donor human milk bank  
449 without first obtaining a license issued by the Commissioner, which shall be renewed biennially. Any donor  
450 human milk bank that operates or does business in the Commonwealth shall be required to obtain a license  
451 from the Commissioner, except as provided in subsection F. A donor human milk bank shall not be required  
452 to obtain a separate license to operate a satellite milk depot.

453 B. The Board shall promulgate regulations that require any donor human milk bank that operates or does  
454 business in the Commonwealth to obtain a license from the Commissioner, in accordance with the provisions  
455 of subsection A of § 32.1-162.15:15.

456 C. Any person establishing or operating a donor human milk bank that is not licensed as required by this  
457 article is guilty of a Class 6 felony.

458 D. No license issued under this article shall be assignable or transferable.

459 E. The Commissioner shall have the authority to enter into licensure recognition agreements with a  
460 licensed out-of-state milk bank, an out-of-state milk bank accredited by a professional association, or an  
461 out-of-state milk bank approved by the Board if it is determined that the Commonwealth lacks access to  
462 donor human milk or to facilitate interstate operation of donor human milk banks with the goal of improving  
463 access to pasteurized donor human milk and human milk-derived products, provided that the Commissioner  
464 determines the donor human milk bank licensing or accreditation standards or requirements of the other  
465 state are substantially equivalent to those established pursuant to this article.

466 F. A donor human milk bank that is actively in good standing in another state that has entered into a  
467 licensure recognition agreement pursuant to subsection E is not subject to the provisions of this article.

468 **§ 32.1-162.15:14. Donor Human Milk Bank Fund established.**

469 There is hereby created in the state treasury a special nonreverting fund to be known as the Donor  
470 Human Milk Bank Fund. The Fund shall be established on the books of the Comptroller. All fees received  
471 under the provisions of this article, all funds appropriated for such purpose, and any gifts, donations, grants,  
472 bequests, and other funds received on behalf of the Fund shall be paid into the state treasury and credited to  
473 the Fund. Interest earned on moneys in the Fund shall remain in the Fund and be credited to it. Any moneys  
474 remaining in the Fund, including interest thereon, at the end of each fiscal year shall not revert to the general  
475 fund but shall remain in the Fund. Moneys in the Fund shall be used solely for the purpose of operating the  
476 donor human milk bank licensure and inspection program established pursuant to this article or supporting  
477 the Virginia Breastfeeding Advisory Committee's efforts to ensure equitable access to donor human milk,  
478 support human milk donation within the Commonwealth, and support the distribution of human milk during  
479 emergencies and disasters. Expenditures and disbursements from the Fund shall be made by the State  
480 Treasurer on warrants issued by the Comptroller upon written request signed by the Commissioner.

481 **§ 32.1-162.15:15. Regulations.**

482 A. The Board shall promulgate regulations that require any donor human milk bank that operates or does  
483 business in the Commonwealth to obtain a license from the Commissioner and that prohibit any donor human  
484 milk bank from operating or doing business in the Commonwealth without a license. Such regulations shall  
485 be in substantial conformity to the standards of health, hygiene, sanitation, construction, and safety as  
486 established and recognized by medical and health care professionals and by specialists in matters of public  
487 health and safety and shall be consistent with the U.S. Food and Drug Administration and Centers for  
488 Disease Control and Prevention guidance and regulations for safe human milk banking.

489 B. The Board shall promulgate regulations for the licensure of donor human milk banks, which shall

490 include (i) a process for licensure and renewal of a license as a donor human milk bank; (ii) appropriate fees  
 491 for licensure, renewal, and inspection of a license as a donor human milk bank; (iii) standards and  
 492 requirements for donor human milk banks to protect the health and safety of the public and ensure the quality  
 493 of donor human milk and human milk-derived products; (iv) provisions for inspections of donor human milk  
 494 banks in accordance with the provisions of § 32.1-162.15:16; and (v) provisions for revocation or denial of a  
 495 license to operate a donor human milk bank in accordance with the provisions of § 32.1-162.15:19, including  
 496 provisions and processes relating to addressing complaints received from the public and disciplinary actions  
 497 for violations of the provisions of this article or of regulations promulgated in accordance with this article.

498 **§ 32.1-162.15:16. Inspections and interviews.**

499 A. Applicants for licensure and licensees shall at all times afford the Commissioner or his representatives  
 500 reasonable opportunity to inspect all of their facilities, books, and records and to interview their agents and  
 501 employees and any person participating in such donor human milk banks or under their custody, control,  
 502 direction, or supervision. Interviews conducted pursuant to this section with persons participating in a donor  
 503 human milk bank operated by or under the custody, control, direction, or supervision of an applicant for  
 504 licensure or a licensee shall be (i) authorized by the person to be interviewed or his legally authorized  
 505 representative and (ii) limited to discussion of issues related to the applicant's or licensee's compliance with  
 506 applicable laws and regulations.

507 B. The Commissioner shall cause every licensed donor human milk bank to be subject to an unannounced  
 508 inspection periodically, but not less often than biennially, in accordance with the provisions of this article  
 509 and regulations of the Board.

510 C. The activities, services, and facilities of each applicant for renewal of the applicant's license as a  
 511 donor human milk bank may be subject to an inspection or examination by the Commissioner to determine if t  
 512 he applicant is in compliance with current regulations of the Board.

513 D. For any donor human milk bank, the Commissioner may authorize such other announced or  
 514 unannounced inspections as the Commissioner considers appropriate. The Commissioner is authorized to  
 515 conduct announced or unannounced inspections or investigations of any donor human milk bank in response  
 516 to receipt of a complaint from the public alleging that such donor human milk bank is substantially out of  
 517 compliance with the terms of its license, is in violation of any provision of this article or any regulation  
 518 promulgated in accordance with the provisions of this article, or is otherwise putting the health, safety, or  
 519 welfare of the public at risk.

520 **§ 32.1-162.15:17. Records and reports.**

521 Every donor human milk bank shall keep such records and make such reports to the Commissioner as the  
 522 Board may require by regulation. The Commissioner shall prescribe and furnish the forms to be used in the  
 523 making of such reports.

524 **§ 32.1-162.15:18. Confidentiality of complainant's identity; retaliation or discrimination against  
 525 complainants prohibited.**

526 A. Whenever the Commissioner conducts inspections and investigations in response to complaints  
 527 received from the public pursuant to subsection D of § 32.1-162.15:16, the identity of the complainant and  
 528 the identity of any child or patient who is the subject of the complaint, or identified therein, shall be  
 529 confidential and shall not be open to inspection by members of the public. Identities of the complainant and  
 530 child or patient who is the subject of the complaint shall be revealed only if a court order so requires.  
 531 Nothing contained herein shall prevent the Commissioner, in his discretion, from disclosing to the donor  
 532 human milk bank the nature of the complaint. Nothing contained herein shall prevent the Department or its  
 533 employees from making reports under Chapter 15 (§ 63.2-1501 et seq.) or Article 2 (§ 63.2-1603 et seq.) of  
 534 Chapter 16 of Title 63.2. If the Commissioner intends to rely, in whole or in part, on any statements made by  
 535 the complainant at any administrative proceeding brought against the donor human milk bank, the  
 536 Commissioner shall disclose the identity of the complainant to the donor human milk bank by a reasonable  
 537 time in advance of such proceeding.

538 B. No donor human milk bank may retaliate or discriminate in any manner against any person who (i) in  
 539 good faith complains or provides information to, or otherwise cooperates with, the Department or any other  
 540 agency of government or any person or entity operating under contract with an agency of government having  
 541 responsibility for protecting the rights of children or patients; (ii) attempts to assert any right protected by  
 542 state or federal law; or (iii) assists any person in asserting such right.

543 **§ 32.1-162.15:19. Disciplinary action generally; civil penalty.**

544 A. The Commissioner may impose disciplinary action in accordance with the regulations promulgated by  
 545 the Board pursuant to subsection G for (i) violating any provision of this article or any regulation adopted in  
 546 accordance with this article the violation of which adversely affects, or is an imminent and substantial threat  
 547 to, the health, safety, or welfare of the public or (ii) permitting, aiding, or abetting the commission of any  
 548 illegal act in a donor human milk bank.

549 B. The disciplinary actions that the Commissioner may impose include:

- 550 1. Revoking or refusing to renew a license or issue a license;
- 551 2. Suspending or refusing to reinstate a license;

552 3. Placing a licensee on probation upon finding that the licensee is substantially out of compliance with  
 553 the terms of its license and that the health, safety, or welfare of the public is at risk;

554 4. Issuing a notice of summary suspension of the license of any donor human milk bank in accordance  
 555 with the provisions of §§ 32.1-162.15:20 and 32.1-162.15:21 during the pendency of any proceeding for  
 556 revocation or denial of a license or other such proceeding upon finding that conditions or practices exist in  
 557 the donor human milk bank that pose an immediate and substantial threat to the health, safety, or welfare of  
 558 the public such that the Commissioner believes that operation of the donor human milk bank should be  
 559 suspended;

560 5. Mandating training for the licensee or licensee's employees or volunteers, with any costs to be borne by  
 561 the licensee, when the Commissioner concludes that the lack of such training has led directly to violations of  
 562 regulations;

563 6. Assessing civil penalties of not more than \$1,000 per violation per day, not to exceed \$25,000 for a  
 564 series of related incidents of noncompliance, upon finding that the donor human milk bank is substantially  
 565 out of compliance with the terms of its license and the health, safety, or welfare of the public is at risk;

566 7. Requiring licensees to contact the purchaser in writing regarding health and safety violations; and

567 8. Requiring submission of and compliance with plans of corrective action, with or without actions  
 568 directed by the Commissioner.

569 C. Any civil penalties collected under this section shall be paid to the Donor Human Milk Bank Fund  
 570 established in § 32.1-162.15:14 after deduction of the administrative costs of the Commissioner and the  
 571 Department in furtherance of this article. A civil penalty that is not appealed shall become due on the first  
 572 day after the appeal period expires. The license of a donor human milk bank that has failed to pay a civil  
 573 penalty due under this section shall not be renewed until the civil penalty has been paid in full, with interest,  
 574 provided that the Commissioner may renew a license when an unpaid civil penalty is the subject of a pending  
 575 appeal.

576 D. An appeal, taken as provided in this article, shall operate to stay any criminal prosecution for  
 577 operation without a license.

578 E. If a license is revoked or refused renewal, a new license may be issued by the Commissioner after:

579 1. Satisfactory evidence is submitted to him that the conditions upon which the revocation or refusal was  
 580 based have been corrected; and

581 2. Proper inspection has been conducted and compliance with all provisions of this article, regulations  
 582 promulgated pursuant to this article, and applicable state and federal law and regulations hereunder has  
 583 been obtained.

584 F. Any disciplinary action the Commissioner imposes against a donor human milk bank that is not  
 585 operated by an agency of the Commonwealth shall be governed by the provisions of § 32.1-162.15:20. Any  
 586 disciplinary action the Commissioner imposes against a donor human milk bank that is operated by an  
 587 agency of the Commonwealth shall be governed by the provisions of § 32.1-162.15:21.

588 G. The Board shall promulgate regulations to implement the provisions of this section, including:

589 1. Criteria for when the imposition of disciplinary action or initiation of court proceedings as specified in  
 590 § 32.1-27, or a combination thereof, is appropriate in order to ensure prompt correction of violations  
 591 involving noncompliance with requirements of any order of the Board or Commissioner or any provision of  
 592 or regulation promulgated pursuant to this article;

593 2. Criteria for imposition of disciplinary action based upon the severity, pervasiveness, duration, and  
 594 degree of risk to the health, safety, or welfare of the public;

595 3. Provisions under which the Commissioner may (i) accept a plan of corrective action, including a  
 596 schedule of compliance, from a donor human milk bank prior to assessing a civil penalty pursuant to  
 597 subdivision B 6 and (ii) reduce or abate the civil penalty amount if the donor human milk bank complies with  
 598 the plan of correction within its terms; and

599 4. Procedures for imposition of disciplinary action consistent with the Administrative Process Act (§  
 600 2.2-4000 et seq.).

601 **§ 32.1-162.15:20. Disciplinary action against privately operated donor human milk banks; notice and  
 602 opportunity to be heard; summary suspension.**

603 A. The Commissioner may take disciplinary action against a donor human milk bank that is not operated  
 604 by an agency of the Commonwealth pursuant to subsection A of § 32.1-162.15:19. Such disciplinary action  
 605 may be in addition to any penalty imposed by law for the violation. Except as provided in subsections B and  
 606 C, the Commissioner shall take no action to impose disciplinary action against any such donor human milk  
 607 bank unless, at least 30 days prior to taking such action, the Commissioner provides the donor human milk  
 608 bank with reasonable notice and an opportunity to be heard by a hearing officer in accordance with §  
 609 2.2-4019 and in accordance with the following:

610 1. Any request for an opportunity to be heard shall be received in writing within 15 days of receipt of a  
 611 notice of imposition of disciplinary action;

612 2. All administrative proceedings under this section shall be separate from the regulatory office of the

613 Department that conducted the inspection, investigation, examination, or review;

614 3. Upon conclusion of any administrative proceeding under this section, the hearing officer shall provide  
615 a recommendation to the Commissioner, including findings of fact, conclusions, and appropriate disciplinary  
616 action; and

617 4. The Commissioner may affirm, modify, or reverse such recommendation and shall issue a final case  
618 decision.

619 B. Pursuant to § 32.1-162.15:19, the Commissioner may issue a notice of summary suspension of the  
620 license of any donor human milk bank against which proceedings are pending if the Commissioner finds that  
621 the conditions or practices existing in such donor human milk bank pose an immediate and substantial threat  
622 to the health, safety, or welfare of the public receiving care such that the continued operation of such donor  
623 human milk bank should be suspended during the pendency of such proceeding. Any notice of summary  
624 suspension issued by the Commissioner shall (i) set forth (a) the summary suspension procedures; (b) the  
625 right to a summary suspension hearing to determine whether the summary suspension is appropriate and the  
626 right to appeal a final order of summary suspension, as provided in this section; (c) the facts and evidence  
627 that form the basis for such summary suspension; and (d) the time, date, and location of the hearing and (ii)  
628 be served on the donor human milk bank or its designee as soon as practicable thereafter by personal service  
629 or certified mail, return receipt requested, to the address of record of the donor human milk bank.

630 C. Any summary suspension hearing initiated pursuant to subsection B shall be presided over by a  
631 hearing officer selected by the Commissioner from a list prepared by the Executive Secretary of the Supreme  
632 Court of Virginia and shall be conducted in accordance with the following procedures:

633 1. The summary suspension hearing shall be held as soon as practicable, but in no event later than 21  
634 days following service of the notice of summary suspension; however, the hearing officer may grant a written  
635 request for a continuance, not to exceed an additional 14 days, for good cause shown.

636 2. Within 14 days after such hearing, the hearing officer shall provide to the Commissioner written  
637 findings and conclusions, together with a recommendation as to whether the license should be summarily  
638 suspended.

639 3. Within 14 days of the receipt of the hearing officer's findings, conclusions, and recommendation, the  
640 Commissioner shall issue a final order of summary suspension or an order that such summary suspension is  
641 not warranted by the facts and circumstances presented. The Commissioner shall adopt the hearing officer's  
642 recommendation unless to do so would be an error of law or Department policy. If the Commissioner rejects  
643 the hearing officer's findings, conclusions, or recommendation, the Commissioner shall state with  
644 particularity the basis for rejection. In issuing a final order of summary suspension, the Commissioner may  
645 choose to suspend the license of the donor human milk bank or to suspend only certain authority of the donor  
646 human milk bank to operate, including the authority to provide certain services or perform certain functions  
647 that the Commissioner determines should be restricted or modified in order to protect the health, safety, or  
648 welfare of the public receiving care. A final order of summary suspension shall include notice that the  
649 licensee may appeal the Commissioner's decision to the appropriate circuit court no later than 10 days  
650 following service of the order.

651 4. In the event that a licensee timely appeals a final order of summary suspension, the sole issue before  
652 the court shall be whether the Commissioner had reasonable grounds to require the licensee to cease  
653 operations during the pendency of the concurrent revocation, denial, or other proceeding. The concurrent  
654 revocation, denial, or other proceeding shall not be affected by the outcome of any hearing on the  
655 appropriateness of the summary suspension.

656 5. A copy of any final order of summary suspension shall be prominently displayed by the donor human  
657 milk bank at each public entrance of the facility, or in lieu thereof, the donor human milk bank may display a  
658 written statement summarizing the terms of the order in a prominent location, printed in a clear and legible  
659 size and typeface, and identifying the location within the facility where the final order of summary suspension  
660 may be reviewed.

661 D. Any time the Commissioner refuses to issue or renew a license or revokes a license for a donor human  
662 milk bank not operated by an agency of the Commonwealth, the provisions of the Administrative Process Act  
663 (§ 2.2-4000 et seq.) shall apply.

664 **§ 32.1-162.15:21. Disciplinary action against donor human milk banks operated by an agency of the**  
665 **Commonwealth; notice of imposition and opportunity to appeal; summary suspension.**

666 A. The Commissioner may take disciplinary action against a donor human milk bank that is operated by  
667 an agency of the Commonwealth pursuant to subsection A of § 32.1-162.15:19. Except as provided in  
668 subsections B and C, the Commissioner shall take no action to impose disciplinary action against a donor  
669 human milk bank that is operated by an agency of the Commonwealth unless, prior to taking such action, the  
670 Commissioner provides:

671 1. No fewer than 45 days prior to imposing any proposed disciplinary action, reasonable notice of  
672 imposition of disciplinary action; and

673 2. The right to appeal any such notice of imposition of disciplinary action, as follows:

674 a. Within 30 days after receiving a notice of imposition of disciplinary action, the licensee shall request in

675 *writing that the Commissioner review the intended disciplinary action and may submit, together with such*  
 676 *request, relevant information, documentation, or other pertinent data supporting its appeal. The*  
 677 *Commissioner shall issue a decision within 60 days after receiving the request and shall have the authority to*  
 678 *uphold the disciplinary action or take whatever action he deems appropriate to resolve the controversy.*

679 *b. If the donor human milk bank disputes the Commissioner's decision, the licensee shall request, within*  
 680 *30 days of receiving the Commissioner's decision, that the Commissioner refer the matter to the Secretary of*  
 681 *Health and Human Resources (the Secretary). The Secretary shall issue a decision within 60 days of*  
 682 *receiving the request for review. The Secretary's decision shall be final and shall not be subject to judicial*  
 683 *review.*

684 *B. Pursuant to § 32.1-162.15:19, the Commissioner may issue a notice of summary suspension of the*  
 685 *license of any donor human milk bank against which proceedings are pending if the Commissioner finds that*  
 686 *the conditions or practices existing in such donor human milk bank pose an immediate and substantial threat*  
 687 *to the health, safety, or welfare of the public receiving care such that the continued operation of such donor*  
 688 *human milk bank should be suspended during the pendency of such proceeding. Any notice of summary*  
 689 *suspension issued by the Commissioner shall (i) set forth (a) the summary suspension procedures; (b) the*  
 690 *right to a summary suspension hearing to determine whether the summary suspension is appropriate and the*  
 691 *right to appeal a final order of summary suspension, as provided in this section; (c) the facts and evidence*  
 692 *that form the basis for such summary suspension; and (d) the time, date, and location of the hearing and (ii)*  
 693 *be served on the licensee or its designee as soon as practicable thereafter by personal service or certified*  
 694 *mail, return receipt requested, to the address of record of the licensee.*

695 *C. Any summary suspension hearing initiated pursuant to subsection B shall be conducted in accordance*  
 696 *with the following procedures:*

697 *1. Such hearing shall be held no later than three business days after the issuance of the notice of the*  
 698 *summary order of suspension and shall be convened by the Commissioner or his designee.*

699 *2. After such hearing, the Commissioner may issue a final order of summary suspension or may find that*  
 700 *such summary suspension is not warranted by the facts and circumstances presented. A final order of*  
 701 *summary suspension shall include notice that the licensee may request, in writing and within three business*  
 702 *days after receiving the Commissioner's decision, that the Commissioner refer the matter to the Secretary of*  
 703 *Health and Human Resources (the Secretary) for resolution within three business days of the referral. Any*  
 704 *determination by the Secretary shall be final and not subject to judicial review.*

705 *3. If the final order of summary suspension is upheld, it shall take effect immediately, and a copy of the*  
 706 *final order of summary suspension shall be prominently displayed by the licensee at each public entrance of*  
 707 *the donor human milk bank. Any concurrent revocation, denial, or other proceedings shall not be affected by*  
 708 *the outcome of any determination by the Secretary.*

709 **§ 32.1-162.15:22. Out-of-state donor human milk procurement.**

710 *A human donor milk bank licensed pursuant to this article may procure human donor milk from a licensed*  
 711 *out-of-state milk bank, an out-of-state milk bank accredited by a professional association, or an out-of-state*  
 712 *milk bank approved by the Board if such bank lacks access to donor human milk or a specific type of milk*  
 713 *prescribed by a health care provider.*

714 **§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and**  
 715 **Human Services pursuant to federal law; administration of plan; contracts with health care providers.**

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

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

724 *2. A provision for determining eligibility for benefits for medically needy individuals which disregards*  
 725 *from countable resources an amount not in excess of \$3,500 for the individual and an amount not in excess of*  
 726 *\$3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual*  
 727 *or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an*  
 728 *individual owned by the individual or his spouse if the cash surrender value of such policies has been*  
 729 *excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or*  
 730 *other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial*  
 731 *expenses;*

732 *3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy*  
 733 *persons whose eligibility for medical assistance is required by federal law to be dependent on the budget*  
 734 *methodology for Aid to Families with Dependent Children, a home means the house and lot used as the*  
 735 *principal residence and all contiguous property. For all other persons, a home shall mean the house and lot*

736 used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive  
 737 of the lot occupied by the house, does not exceed \$5,000. In any case in which the definition of home as  
 738 provided here is more restrictive than that provided in the state plan for medical assistance services in  
 739 Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal  
 740 residence and all contiguous property essential to the operation of the home regardless of value;

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

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

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

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

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

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

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

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

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

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

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

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

795 16. A provision for payment of medical assistance for low-dose screening mammograms for determining  
 796 the presence of occult breast cancer. Such coverage shall make available one screening mammogram to

797 persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such  
798 mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of  
799 the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray  
800 tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than  
801 one rad mid-breast, two views of each breast;

802 17. A provision, when in compliance with federal law and regulation and approved by the Centers for  
803 Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to  
804 Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program  
805 and may be provided by school divisions, regardless of whether the student receiving care has an  
806 individualized education program or whether the health care service is included in a student's individualized  
807 education program. Such services shall include those covered under the state plan for medical assistance  
808 services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in §  
809 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for  
810 health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care  
811 provider who provides health care services through telemedicine shall be required to use proprietary  
812 technology or applications in order to be reimbursed for providing telemedicine services;

813 18. A provision for payment of medical assistance services for liver, heart and lung transplantation  
814 procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or  
815 surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and  
816 application of the procedure in treatment of the specific condition have been clearly demonstrated to be  
817 medically effective and not experimental or investigational; (iii) prior authorization by the Department of  
818 Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant  
819 center where the surgery is proposed to be performed have been used by the transplant team or program to  
820 determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the  
821 patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible  
822 terminal state; and (vii) the transplant is likely to prolong the patient's life and restore a range of physical and  
823 social functioning in the activities of daily living;

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

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

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

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

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

851 24. A provision, when authorized by and in compliance with federal law, to establish a public-private  
852 long-term care partnership program between the Commonwealth of Virginia and private insurance companies  
853 that shall be established through the filing of an amendment to the state plan for medical assistance services  
854 by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid  
855 costs for long-term care by delaying or eliminating dependence on Medicaid for such services through  
856 encouraging the purchase of private long-term care insurance policies that have been designated as qualified  
857 state long-term care insurance partnerships and may be used as the first source of benefits for the participant's

858 long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and  
859 estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

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

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

868 For the purposes of this subdivision, a health care provider duly licensed by the Commonwealth who  
869 provides health care services exclusively through telemedicine services shall not be required to maintain a  
870 physical presence in the Commonwealth to be considered an eligible provider for enrollment as a Medicaid  
871 provider.

872 For the purposes of this subdivision, a telemedicine services provider group with health care providers  
873 duly licensed by the Commonwealth shall not be required to have an in-state service address to be eligible to  
874 enroll as a Medicaid vendor or Medicaid provider group.

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

879 27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month  
880 supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not  
881 impose any utilization controls or other forms of medical management limiting the supply of hormonal  
882 contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this  
883 subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of  
884 self-administered hormonal contraceptives at one time or (ii) exclude coverage for hormonal contraceptives  
885 as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive  
886 purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent  
887 pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone,  
888 that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration  
889 for such purpose;

890 28. A provision for payment of medical assistance for remote patient monitoring services provided via  
891 telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants  
892 and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months  
893 following the date of such surgery; and (v) patients with a chronic or acute health condition who have had  
894 two or more hospitalizations or emergency department visits related to such health condition in the previous  
895 12 months when there is evidence that the use of remote patient monitoring is likely to prevent readmission  
896 of such patient to a hospital or emergency department. For the purposes of this subdivision, "remote patient  
897 monitoring services" means the use of digital technologies to collect medical and other forms of health data  
898 from patients in one location and electronically transmit that information securely to health care providers in  
899 a different location for analysis, interpretation, and recommendations, and management of the patient.  
900 "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood  
901 pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence  
902 monitoring, and interactive videoconferencing with or without digital image upload;

903 29. A provision for the payment of medical assistance for provider-to-provider consultations that is no  
904 more restrictive than, and is at least equal in amount, duration, and scope to, that available through the fee-  
905 for-service program;

906 30. A provision for payment of the originating site fee to emergency medical services agencies for  
907 facilitating synchronous telehealth visits with a distant site provider delivered to a Medicaid member. As used  
908 in this subdivision, "originating site" means any location where the patient is located, including any medical  
909 care facility or office of a health care provider, the home of the patient, the patient's place of employment, or  
910 any public or private primary or secondary school or postsecondary institution of higher education at which  
911 the person to whom telemedicine services are provided is located;

912 31. A provision for the payment of medical assistance for targeted case management services for  
913 individuals with severe traumatic brain injury;

914 32. A provision for payment of medical assistance for the initial purchase or replacement of complex  
915 rehabilitative technology manual and power wheelchair bases and related accessories, as defined by the  
916 Department's durable medical equipment program policy, for patients who reside in nursing facilities. Initial  
917 purchase or replacement may be contingent upon (i) determination of medical necessity; (ii) requirements in  
918 accordance with regulations established through the Department's durable medical equipment program

919 policy; and (iii) exclusive use by the nursing facility resident. Recipients of medical assistance shall not be  
 920 required to pay any deductible, coinsurance, copayment, or patient costs related to the initial purchase or  
 921 replacement of complex rehabilitative technology manual and power wheelchair bases and related  
 922 accessories; ~~and~~

923 33. A provision for payment of medical assistance for remote ultrasound procedures and remote fetal  
 924 non-stress tests. Such provision shall utilize established CPT codes for these procedures and shall apply when  
 925 the patient is in a residence or other off-site location from the patient's provider that provides the same  
 926 standard of care. The provision shall provide for reimbursement only when a provider uses digital technology  
 927 (i) to collect medical and other forms of health data from a patient and electronically transmit that  
 928 information securely to a health care provider in a different location for interpretation and recommendation;  
 929 (ii) that is compliant with the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C.  
 930 § 1320d et seq.); and (iii) that is approved by the U.S. Food and Drug Administration. For fetal non-stress  
 931 tests under CPT Code 59025, the provision shall provide for reimbursement only if such test (a) is conducted  
 932 with a place of service modifier for at-home monitoring and (b) uses remote monitoring solutions that are  
 933 approved by the U.S. Food and Drug Administration for on-label use to monitor fetal heart rate, maternal  
 934 heart rate, and uterine activity; *and*

935 34. *A provision for the payment of medical assistance for the provision of pasteurized donor human milk*  
 936 *and human milk-derived products for an inpatient or outpatient infant younger than 12 months corrected age,*  
 937 *as defined in § 32.1-162.15:12, (i) who lacks sufficient access to his mother's maternal breast milk, (ii) for*  
 938 *whom a licensed health care provider has issued a written order for the provision of such milk or*  
 939 *milk-derived product, and (iii) who meets one of the following medical criteria:*

940 *a. Birth weight less than or equal to 1,500 grams;*

941 *b. Birth less than or equal to 34 weeks' gestation;*

942 *c. A diagnosis of:*

943 *(1) A health condition that places the infant at a high risk for the development of necrotizing enterocolitis,*  
 944 *bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity;*

945 *(2) An immunologic deficiency or the need for an organ or bone marrow transplant; or*

946 *(3) Any other serious congenital or acquired condition for which the use of pasteurized donor human milk*  
 947 *is medically necessary and supports the treatment and recovery of the infant as determined by the*  
 948 *Department.*

949 *Pasteurized donor human milk obtained pursuant to this subdivision shall be obtained from a donor*  
 950 *human milk bank that is licensed by the Department of Health pursuant to Article 9 (§ 32.1-162.15:12 et seq.)*  
 951 *of Chapter 5 of Title 32.1.*

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

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

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

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

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

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

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

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

978 In the event conforming amendments to the state plan for medical assistance services are adopted, the  
 979 Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of

980 Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of  
 981 Regulations that such amendment is necessary to meet the requirements of federal law or regulations or  
 982 because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are  
 983 necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia  
 984 shall only remain in effect until July 1 following adjournment of the next regular session of the General  
 985 Assembly unless enacted into law.

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

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

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

996 3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or  
 997 contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to  
 998 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  
 999 C.F.R. § 1002.212.

1000 4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or  
 1001 contract, with a provider who is or has been a principal in a professional or other corporation when such  
 1002 corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316,  
 1003 or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to  
 1004 42 C.F.R. Part 1002.

1005 5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of §  
 1006 32.1-162.13.

1007 For the purposes of this subsection, "provider" may refer to an individual or an entity.

1008 E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to  
 1009 subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a  
 1010 post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et  
 1011 seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

1012 The Director may consider aggravating and mitigating factors including the nature and extent of any  
 1013 adverse impact the agreement or contract denial or termination may have on the medical care provided to  
 1014 Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection  
 1015 D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to  
 1016 lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

1017 F. When the services provided for by such plan are services which a marriage and family therapist,  
 1018 clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to  
 1019 render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly  
 1020 licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed  
 1021 clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for  
 1022 covered services as provided in the state plan. The Board shall promulgate regulations which reimburse  
 1023 licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers,  
 1024 licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria,  
 1025 including the professional credentials required for licensure.

1026 G. The Board shall prepare and submit to the Secretary of the United States Department of Health and  
 1027 Human Services such amendments to the state plan for medical assistance services as may be permitted by  
 1028 federal law to establish a program of family assistance whereby children over the age of 18 years shall make  
 1029 reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical  
 1030 assistance under the plan to their parents.

1031 H. The Department of Medical Assistance Services shall:

1032 1. Include in its provider networks and all of its health maintenance organization contracts a provision for  
 1033 the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and  
 1034 who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for  
 1035 medically necessary assessment and treatment services, when such services are delivered by a provider which  
 1036 specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable  
 1037 expertise, as determined by the Director.

1038 2. Amend the Medallion II waiver and its implementing regulations to develop and implement an  
 1039 exception, with procedural requirements, to mandatory enrollment for certain children between birth and age  
 1040 three certified by the Department of Behavioral Health and Developmental Services as eligible for services

1041 pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

1042 3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors  
1043 and enrolled providers for the provision of health care services under Medicaid and the Family Access to  
1044 Medical Insurance Security Plan established under § 32.1-351.

1045 4. Require any managed care organization with which the Department enters into an agreement for the  
1046 provision of medical assistance services to include in any contract between the managed care organization  
1047 and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of  
1048 the pharmacy benefits manager from conducting spread pricing with regards to the managed care  
1049 organization's managed care plans. For the purposes of this subdivision:

1050 "Pharmacy benefits management" means the administration or management of prescription drug benefits  
1051 provided by a managed care organization for the benefit of covered individuals.

1052 "Pharmacy benefits manager" means a person that performs pharmacy benefits management.

1053 "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager  
1054 charges a managed care plan a contracted price for prescription drugs, and the contracted price for the  
1055 prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the  
1056 pharmacist or pharmacy for pharmacist services.

1057 I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible  
1058 recipients with special needs. The Board shall promulgate regulations regarding these special needs patients,  
1059 to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as  
1060 defined by the Board.

1061 J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement  
1062 Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this  
1063 section. Agreements made pursuant to this subsection shall comply with federal law and regulation.

1064 K. When the services provided for by such plan are services by a pharmacist, pharmacy technician, or  
1065 pharmacy intern (i) performed under the terms of a collaborative agreement as defined in § 54.1-3300 and  
1066 consistent with the terms of a managed care contractor provider contract or the state plan or (ii) related to  
1067 services and treatment in accordance with § 54.1-3303.1, the Department shall provide reimbursement for  
1068 such service.

1069 **§ 38.2-3418.22. Coverage for expenses incurred in the provision of pasteurized donor human milk.**

1070 A. *Notwithstanding the provisions of § 38.2-3419 or subdivision A 1 of § 38.2-6506, each insurer*  
1071 *proposing to issue individual or group accident and sickness insurance policies providing hospital, medical*  
1072 *and surgical, or major medical coverage on an expense-incurred basis; each corporation providing*  
1073 *individual or group accident and sickness subscription contracts; and each health maintenance organization*  
1074 *providing a health care plan for health care services shall provide inpatient and outpatient coverage for*  
1075 *expenses incurred in the provision of pasteurized donor human milk and human milk-derived products,*  
1076 *provided that coverage is included for the provision of pasteurized donor human milk and human*  
1077 *milk-derived products for an infant younger than 12 months corrected age, as defined in § 32.1-162.15:12, (i)*  
1078 *who lacks sufficient access to his mother's maternal breast milk, (ii) for whom a licensed health care provider*  
1079 *has issued a written order for the provision of such milk or milk-derived product, and (iii) who meets one of*  
1080 *the following medical criteria:*

1081 1. *Birth weight less than or equal to 1,500 grams;*

1082 2. *Birth less than or equal to 34 weeks gestation;*

1083 3. *A diagnosis of:*

1084 a. *A health condition that places the infant at a high risk for the development of necrotizing enterocolitis,*  
1085 *bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity;*

1086 b. *An immunologic deficiency or the need for an organ or bone marrow transplant; or*

1087 c. *Any other serious congenital or acquired condition for which the use of pasteurized donor human milk*  
1088 *is medically necessary and supports the treatment and recovery of the infant as determined by the*  
1089 *Department.*

1090 *Pasteurized donor human milk obtained pursuant to this subsection shall be obtained from a donor*  
1091 *human milk bank that is licensed by the Department of Health pursuant to Article 9 (§ 32.1-162.15:12 et seq.)*  
1092 *of Chapter 5 of Title 32.1.*

1093 B. *Nothing in this section shall preclude the insurer, corporation, or health maintenance organization*  
1094 *from performing utilization review, including periodic review of the medical necessity of a particular service.*

1095 C. *No insurer, corporation, or health maintenance organization shall impose upon any person receiving*  
1096 *benefits pursuant to this section any copayment, fee, or condition that is not equally imposed upon all*  
1097 *individuals in the same benefit category.*

1098 D. *The provisions of this section shall apply to any policy, contract, or plan delivered, issued for delivery,*  
1099 *or renewed in the Commonwealth on and after January 1, 2027.*

1100 E. *The provisions of this section shall not apply to short-term travel, accident-only, or limited or specified*  
1101 *disease policies; contracts designed for issuance to persons eligible for coverage under Title XVIII of the*

1102 *Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental*  
1103 *plans; or short-term nonrenewable policies of not more than six months' duration.*

1104 **§ 38.2-4319. Statutory construction and relationship to other laws.**

1105 A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter,  
1106 §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225,  
1107 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-316.1, 38.2-316.2, 38.2-322, 38.2-325, 38.2-326, 38.2-400,  
1108 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-629, Chapter 9 (§ 38.2-900 et  
1109 seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, and 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), §  
1110 38.2-1315.1, and Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.), 5 (§ 38.2-1322 et seq.), 5.1 (§  
1111 38.2-1334.3 et seq.), and 5.2 (§ 38.2-1334.11 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.), 2 (§  
1112 38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, Chapter 15 (§ 38.2-1500 et seq.), Chapter 17 (§  
1113 38.2-1700 et seq.), §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3406.1,  
1114 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.20, 38.2-3411, 38.2-3411.2, 38.2-3411.3,  
1115 38.2-3411.4, 38.2-3412.1, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.19, 38.2-3418.21, 38.2-3418.22,  
1116 38.2-3419.1, and 38.2-3430.1 through 38.2-3454, Articles 8 (§ 38.2-3461 et seq.) and 9 (§ 38.2-3465 et seq.)  
1117 of Chapter 34, § 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1,  
1118 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3540.2, 38.2-3541.2, 38.2-3542,  
1119 and 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 35.1 (§ 38.2-3556 et seq.), §  
1120 38.2-3610, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et  
1121 seq.), Chapter 65 (§ 38.2-6500 et seq.), and Chapter 66 (§ 38.2-6600 et seq.) shall be applicable to any health  
1122 maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or  
1123 health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§  
1124 38.2-4200 et seq.) except with respect to the activities of its health maintenance organization.

1125 B. For plans administered by the Department of Medical Assistance Services that provide benefits  
1126 pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except  
1127 this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200,  
1128 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322,  
1129 38.2-325, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, and 38.2-600 through 38.2-629,  
1130 Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, and 38.2-1306.1, Article 2 (§  
1131 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.), 5 (§  
1132 38.2-1322 et seq.), 5.1 (§ 38.2-1334.3 et seq.), and 5.2 (§ 38.2-1334.11 et seq.) of Chapter 13, Articles 1 (§  
1133 38.2-1400 et seq.), 2 (§ 38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, §§ 38.2-3401,  
1134 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6, 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and  
1135 38.2-3407.9:02, subsection E of § 38.2-3407.10, §§ 38.2-3407.10:1, 38.2-3407.11, 38.2-3407.11:3,  
1136 38.2-3407.13, 38.2-3407.13:1, 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3418.16,  
1137 38.2-3419.1, 38.2-3430.1 through 38.2-3437, and 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of  
1138 § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1,  
1139 38.2-3540.2, 38.2-3541.2, 38.2-3542, and 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§  
1140 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.), Chapter 65 (§ 38.2-6500 et seq.), and Chapter 66 (§  
1141 38.2-6600 et seq.) shall be applicable to any health maintenance organization granted a license under this  
1142 chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in  
1143 conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) except with respect to the activities  
1144 of its health maintenance organization.

1145 C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall  
1146 not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

1147 D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice  
1148 of medicine. All health care providers associated with a health maintenance organization shall be subject to  
1149 all provisions of law.

1150 E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health  
1151 maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer  
1152 coverage to or accept applications from an employee who does not reside within the health maintenance  
1153 organization's service area.

1154 F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B  
1155 shall be construed to mean and include "health maintenance organizations" unless the section cited clearly  
1156 applies to health maintenance organizations without such construction.

1157 **2. That the provisions of this act shall become effective on July 1, 2026.**

1158 **2. That the provisions of this act may result in a net increase in periods of imprisonment or**  
1159 **commitment. Pursuant to § 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary**  
1160 **appropriation cannot be determined for periods of imprisonment in state adult correctional facilities;**  
1161 **therefore, Chapter 2 of the Acts of Assembly of 2024, Special Session I, requires the Virginia Criminal**  
1162 **Sentencing Commission to assign a minimum fiscal impact of \$50,000. Pursuant to § 30-19.1:4 of the**

**1163 Code of Virginia, the estimated amount of the necessary appropriation cannot be determined for**  
**1164 periods of commitment to the custody of the Department of Juvenile Justice.**