

SENATE BILL NO. 1186

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Labor and Commerce

on _____)

(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

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.

11. Include coverage providing a minimum stay in the hospital of not less than 48 hours for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of breast cancer. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate.

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

13. Permit any individual covered under the plan direct access to the health care services of a participating specialist (i) authorized to provide services under the plan and (ii) selected by the covered individual. The plan shall have a procedure by which an individual who has an ongoing special condition may, after consultation with the primary care physician, receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care related to the initial specialty care referral. If such an individual's care would most appropriately be coordinated by such a specialist, the plan shall refer the individual to a specialist. For the purposes of this subdivision, "special condition" means a condition or disease that is (i) life-threatening, degenerative, or disabling and (ii) requires specialized medical care over a prolonged period of time. Within the treatment period authorized by the referral, such specialist shall be permitted to treat the individual without a further referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services related to the initial referral as the individual's primary care provider would otherwise be permitted to provide or authorize. The plan shall have a procedure by which an individual who has an ongoing special condition that requires ongoing care from a specialist may receive a standing referral to such specialist for the treatment of the special condition. If the primary care provider, in consultation with the plan and the specialist, if any, determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to a specialist. Nothing contained herein shall prohibit the plan from requiring a participating specialist to provide written notification to the covered individual's primary care physician of any visit to 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 with a corrected age of six months or younger, 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

beneficiaries. Neither the General Assembly nor any public officer, employee, or agency shall use or authorize the use of such trust funds for any purpose other than as provided in law for benefits, refunds, and administrative expenses, including but not limited to legislative oversight of the health insurance fund.

D. For the purposes of this section:

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

"Standard reference compendia" means:

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

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

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

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

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

statement.

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

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

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

Article 9.

Donor Human Milk Banks.

§ 32.1-162.15:12. Definitions.

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

"Collect" means to obtain human breast milk from a donor for the purpose of selling or distributing donor human milk or human milk-derived products to children other than the donor's own child.

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

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

437 *the 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, to*
439 *include 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 donor human milk by a licensed donor human*
442 *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.*

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

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

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

B. The Board is authorized to promulgate regulations and schedules for fees to be charged for the operation of the donor human milk bank licensure and inspection program.

§ 32.1-162.15:15. Regulations.

A. The Board shall promulgate regulations that require any donor human milk bank that operates or does business in the Commonwealth to obtain a license from the Commissioner and that prohibit any donor human milk bank from operating or doing business in the Commonwealth unless such donor human milk bank is licensed pursuant to this article. Such regulations shall be in substantial conformity to the standards of health, hygiene, sanitation, construction, and safety as established and recognized by medical and health care professionals and by specialists in matters of public health and safety and shall be consistent with the U.S. Food and Drug Administration and Centers for Disease Control and Prevention guidance and regulations for safe human milk banking.

B. The Board shall promulgate regulations for the licensure of donor human milk banks, which shall include (i) a process for licensure and renewal of a license as a donor human milk bank, (ii) appropriate fees for licensure and renewal of a license as a donor human milk bank, (iii) standards and requirements for

495 donor human milk banks to protect the health and safety of the public and ensure the quality of donor human
496 milk and human milk-derived products, (iv) provisions for inspections of donor human milk banks in
497 accordance with the provisions of § 32.1-162.15:16, and (v) provisions for revocation or denial of a license
498 to operate a donor human milk bank in accordance with the provisions of § 32.1-162.15:19, including
499 provisions and processes relating to addressing complaints received from the public relating to and
500 disciplinary actions for violations of the provisions of this article or of regulations promulgated in
501 accordance with this article.

502 § 32.1-162.15:16. *Inspections and interviews.*

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

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

514 C. The activities, services, and facilities of each applicant for renewal of the applicant's license as a
515 donor human milk bank may be subject to an inspection or examination by the Commissioner to determine if
516 the applicant is in compliance with current regulations of the Board.

517 D. For any donor human milk bank, the Commissioner may authorize such other announced or
518 unannounced inspections as the Commissioner considers appropriate.

519 E. The Commissioner is authorized to conduct announced or unannounced inspections or investigations of
520 any donor human milk bank in response to receipt of a complaint from the public alleging that such donor
521 human milk bank is substantially out of compliance with the terms of its license, is in violation of any
522 provision of this article or any regulation promulgated in accordance with the provisions of this article, or is
523 otherwise putting the health, safety, or welfare of the public at risk.

§ 32.1-162.15:17. Records and reports.

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

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

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

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

§ 32.1-162.15:19. Disciplinary action generally; monetary penalty.

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

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

554 *1. Revoking or refusing to renew a license or to issue a license;*

555 *2. Suspending or refusing to reinstate a license;*

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

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

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

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

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

571 *8. Requiring submission of and compliance with plans of corrective action, with or without actions*
572 *directed by the Commissioner.*

573 *C. Any monetary penalties collected under this section shall be paid in equal portions to the Physician*
574 *Loan Repayment Program established in § 32.1-122.6:1, the Nurse Loan Repayment Program established in*
575 *§ 32.1-122.6:04, and the Nursing Scholarship and Loan Repayment Fund established in § 54.1-3011.2 after*
576 *deduction of the administrative costs of the Commissioner and the Department in furtherance of this article.*
577 *A monetary penalty that is not appealed shall become due on the first day after the appeal period expires.*
578 *The license of a donor human milk bank that has failed to pay a monetary penalty due under this section shall*
579 *not be renewed until the monetary penalty has been paid in full, with interest, provided that the*
580 *Commissioner may renew a license when an unpaid monetary penalty is the subject of a pending appeal.*

581 *D. An appeal, taken as provided in this article, shall operate to stay any criminal prosecution for*

operation without a license.

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

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

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

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

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

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

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

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

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

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

A. The Commissioner may take disciplinary action against a donor human milk bank that is not operated by an agency of the Commonwealth pursuant to subsection A of § 32.1-162.15:19. Such disciplinary action may be in addition to any penalty imposed by law for the violation. Except as provided in subsections B and

611 *C, the Commissioner shall take no action to impose disciplinary action against any such donor human milk*
612 *bank unless, at least 30 days prior to taking such action, the Commissioner provides the donor human milk*
613 *bank with reasonable notice and an opportunity to be heard by the Commissioner's presiding officer in*
614 *accordance with § 2.2-4019 and in accordance with the following:*

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

617 *2. All administrative proceedings under this section shall be separate from the regulatory office of the*
618 *Department that conducted the inspection, investigation, examination, or review;*

619 *3. Upon conclusion of any administrative proceeding under this section, the presiding officer shall*
620 *provide a recommendation to the Commissioner, including findings of fact, conclusions, and appropriate*
621 *disciplinary action; and*

622 *4. The Commissioner may affirm, modify, or reverse such recommendation and shall issue a final case*
623 *decision.*

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

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

638 *1. The summary suspension hearing shall be held as soon as practicable, but in no event later than 21*
639 *days following service of the notice of summary suspension; however, the hearing officer may grant a written*

640 *request for a continuance, not to exceed an additional 14 days, for good cause shown.*

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

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

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

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

666 D. *Any time the Commissioner refuses to issue or renew a license or revokes a license for a donor human*
667 *milk bank not operated by an agency of the Commonwealth, the provisions of the Administrative Process Act*
668 *(§ 2.2-4000 et seq.) shall apply.*

669 § 32.1-162.15:21. *Disciplinary action against donor human milk banks operated by an agency of the*
670 *Commonwealth; notice of imposition and opportunity to appeal; summary suspension.*

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

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

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

679 a. *Within 30 days after receiving a notice of imposition of disciplinary action, the licensee shall request in*
680 *writing that the Commissioner review the intended disciplinary action and may submit, together with such*
681 *request, relevant information, documentation, or other pertinent data supporting its appeal. The*
682 *Commissioner shall issue a decision within 60 days after receiving the request and shall have the authority to*
683 *uphold the disciplinary action or take whatever action he deems appropriate to resolve the controversy.*

684 b. *If the donor human milk bank disputes the Commissioner's decision, the licensee shall request, within*
685 *30 days of receiving the Commissioner's decision, that the Commissioner refer the matter to the Secretary of*
686 *Health and Human Resources (the Secretary). The Secretary shall issue a decision within 60 days of*
687 *receiving the request for review. The Secretary's decision shall be final and shall not be subject to judicial*
688 *review.*

689 B. *Pursuant to § 32.1-162.15:19, the Commissioner may issue a notice of summary suspension of the*
690 *license of any donor human milk bank against which proceedings are pending if the Commissioner finds that*
691 *the conditions or practices existing in such donor human milk bank pose an immediate and substantial threat*
692 *to the health, safety, or welfare of the public receiving care such that the continued operation of such donor*
693 *human milk bank should be suspended during the pendency of such proceeding. Any notice of summary*
694 *suspension issued by the Commissioner shall (i) set forth (a) the summary suspension procedures, including*
695 *those for a hearing to determine whether summary suspension is appropriate and the right of review as*
696 *provided in this section; (b) the facts and evidence that formed the basis on which the summary order of*
697 *suspension is sought; and (c) the time, date, and location of a hearing to determine whether the suspension is*

appropriate and (ii) be served on the licensee or its designee as soon as practicable thereafter by personal service or certified mail, return receipt requested, to the address of record of the licensee.

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

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

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

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

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

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

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

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

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the

727 Department of Social Services or placed through state and local subsidized adoptions to the extent permitted
728 under federal statute;

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

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

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

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

750 6. A provision for payment of medical assistance on behalf of pregnant women which provides for
751 payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most
752 current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American
753 Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for
754 Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists.
755 Payment shall be made for any postpartum home visit or visits for the mothers and the children which are

within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

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

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

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

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

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

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

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient

785 treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care
786 following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or
787 trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient
788 coverage where the attending physician in consultation with the patient determines that a shorter period of
789 hospital stay is appropriate;

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

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

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

807 17. A provision, when in compliance with federal law and regulation and approved by the Centers for
808 Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to
809 Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program
810 and may be provided by school divisions, regardless of whether the student receiving care has an
811 individualized education program or whether the health care service is included in a student's individualized
812 education program. Such services shall include those covered under the state plan for medical assistance
813 services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in §

1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

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

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

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

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

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention

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

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

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

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

868 26. A provision for the payment of medical assistance for medically necessary health care services
869 provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or
870 whether the patient is accompanied by a health care provider at the time such services are provided. No health
871 care provider who provides health care services through telemedicine services shall be required to use

proprietary technology or applications in order to be reimbursed for providing telemedicine services.

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

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

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

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

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic or acute health condition who have had two or more hospitalizations or emergency department visits related to such health condition in the previous 12 months when there is evidence that the use of remote patient monitoring is likely to prevent readmission

901 of such patient to a hospital or emergency department. For the purposes of this subdivision, "remote patient
902 monitoring services" means the use of digital technologies to collect medical and other forms of health data
903 from patients in one location and electronically transmit that information securely to health care providers in
904 a different location for analysis, interpretation, and recommendations, and management of the patient.
905 "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood
906 pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence
907 monitoring, and interactive videoconferencing with or without digital image upload;

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

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

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

919 32. A provision for payment of medical assistance for the initial purchase or replacement of complex
920 rehabilitative technology manual and power wheelchair bases and related accessories, as defined by the
921 Department's durable medical equipment program policy, for patients who reside in nursing facilities. Initial
922 purchase or replacement may be contingent upon (i) determination of medical necessity; (ii) requirements in
923 accordance with regulations established through the Department's durable medical equipment program
924 policy; and (iii) exclusive use by the nursing facility resident. Recipients of medical assistance shall not be
925 required to pay any deductible, coinsurance, copayment, or patient costs related to the initial purchase or
926 replacement of complex rehabilitative technology manual and power wheelchair bases and related
927 accessories; ~~and~~

928 33. A provision for payment of medical assistance for remote ultrasound procedures and remote fetal
929 non-stress tests. Such provision shall utilize established CPT codes for these procedures and shall apply when

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

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

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

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

c. A diagnosis of:

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

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

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

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

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and

959 that the health, safety, security, rights and welfare of patients are ensured.

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

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

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

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

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

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

983 In the event conforming amendments to the state plan for medical assistance services are adopted, the
984 Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of
985 Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of
986 Regulations that such amendment is necessary to meet the requirements of federal law or regulations or
987 because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are

988 necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia
989 shall only remain in effect until July 1 following adjournment of the next regular session of the General
990 Assembly unless enacted into law.

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

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

995 2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health
996 care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract
997 shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon
998 appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or
999 contract. Such provider may also apply to the Director for reconsideration of the agreement or contract
1000 termination if the conviction is not appealed, or if it is not reversed upon appeal.

1001 3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or
1002 contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to
1003 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
1004 C.F.R. § 1002.212.

1005 4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or
1006 contract, with a provider who is or has been a principal in a professional or other corporation when such
1007 corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316,
1008 or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to
1009 42 C.F.R. Part 1002.

1010 5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of §
1011 32.1-162.13.

1012 For the purposes of this subsection, "provider" may refer to an individual or an entity.

1013 E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to
1014 subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a
1015 post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et
1016 seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

1017 The Director may consider aggravating and mitigating factors including the nature and extent of any
1018 adverse impact the agreement or contract denial or termination may have on the medical care provided to
1019 Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection
1020 D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to
1021 lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

1022 F. When the services provided for by such plan are services which a marriage and family therapist,
1023 clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to
1024 render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly
1025 licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed
1026 clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for
1027 covered services as provided in the state plan. The Board shall promulgate regulations which reimburse
1028 licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers,
1029 licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria,
1030 including the professional credentials required for licensure.

1031 G. The Board shall prepare and submit to the Secretary of the United States Department of Health and
1032 Human Services such amendments to the state plan for medical assistance services as may be permitted by
1033 federal law to establish a program of family assistance whereby children over the age of 18 years shall make
1034 reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical
1035 assistance under the plan to their parents.

1036 H. The Department of Medical Assistance Services shall:

1037 1. Include in its provider networks and all of its health maintenance organization contracts a provision for
1038 the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and
1039 who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for
1040 medically necessary assessment and treatment services, when such services are delivered by a provider which
1041 specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable
1042 expertise, as determined by the Director.

1043 2. Amend the Medallion II waiver and its implementing regulations to develop and implement an
1044 exception, with procedural requirements, to mandatory enrollment for certain children between birth and age
1045 three certified by the Department of Behavioral Health and Developmental Services as eligible for services

1046 pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

1047 3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors
1048 and enrolled providers for the provision of health care services under Medicaid and the Family Access to
1049 Medical Insurance Security Plan established under § 32.1-351.

1050 4. Require any managed care organization with which the Department enters into an agreement for the
1051 provision of medical assistance services to include in any contract between the managed care organization
1052 and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of
1053 the pharmacy benefits manager from conducting spread pricing with regards to the managed care
1054 organization's managed care plans. For the purposes of this subdivision:

1055 "Pharmacy benefits management" means the administration or management of prescription drug benefits
1056 provided by a managed care organization for the benefit of covered individuals.

1057 "Pharmacy benefits manager" means a person that performs pharmacy benefits management.

1058 "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager
1059 charges a managed care plan a contracted price for prescription drugs, and the contracted price for the
1060 prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the
1061 pharmacist or pharmacy for pharmacist services.

1062 I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible
1063 recipients with special needs. The Board shall promulgate regulations regarding these special needs patients,
1064 to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as
1065 defined by the Board.

1066 J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement
1067 Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this
1068 section. Agreements made pursuant to this subsection shall comply with federal law and regulation.

1069 K. When the services provided for by such plan are services by a pharmacist, pharmacy technician, or
1070 pharmacy intern (i) performed under the terms of a collaborative agreement as defined in § 54.1-3300 and
1071 consistent with the terms of a managed care contractor provider contract or the state plan or (ii) related to
1072 services and treatment in accordance with § 54.1-3303.1, the Department shall provide reimbursement for
1073 such service.

1074 § 38.2-3418.22. *Coverage for expenses incurred in the provision of pasteurized donor human milk.*

1075 A. Notwithstanding the provisions of § 38.2-3419 or subdivision A 1 of § 38.2-6506, each insurer
1076 proposing to issue individual or group accident and sickness insurance policies providing hospital, medical
1077 and surgical, or major medical coverage on an expense-incurred basis; each corporation providing
1078 individual or group accident and sickness subscription contracts; and each health maintenance organization
1079 providing a health care plan for health care services shall provide inpatient and outpatient coverage for
1080 expenses incurred in the provision of pasteurized donor human milk and human milk-derived products,
1081 provided that coverage is included for the provision of pasteurized donor human milk and human
1082 milk-derived products for an infant with a corrected age of six months or younger, as defined in §
1083 32.1-162.15:12, (i) who lacks sufficient access to his mother's maternal breast milk, (ii) for whom a licensed
1084 health care provider has issued a written order for the provision of such milk or milk-derived product, and
1085 (iii) who meets one of the following medical criteria:

1086 1. Birth weight less than or equal to 1,500 grams;

1087 2. Birth less than or equal to 34 weeks gestation;

1088 3. A diagnosis of:

1089 a. A health condition that places the infant at a high risk for the development of necrotizing enterocolitis,
1090 bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity;

1091 b. An immunologic deficiency or the need for an organ or bone marrow transplant; or

1092 c. Any other serious congenital or acquired condition for which the use of pasteurized donor human milk
1093 is medically necessary and supports the treatment and recovery of the infant as determined by the
1094 Department.

1095 Pasteurized donor human milk obtained pursuant to this subsection shall be obtained from a donor
1096 human milk bank that is licensed by the Department of Health pursuant to Article 9 (§ 32.1-162.15:12 et seq.)
1097 of Chapter 5 of Title 32.1.

1098 B. Nothing in this section shall preclude the insurer, corporation, or health maintenance organization
1099 from performing utilization review, including periodic review of the medical necessity of a particular service.

1100 C. No insurer, corporation, or health maintenance organization shall impose upon any person receiving
1101 benefits pursuant to this section any copayment, fee, or condition that is not equally imposed upon all
1102 individuals in the same benefit category.

1103 D. The provisions of this section shall apply to any policy, contract, or plan delivered, issued for delivery,

1104 *or renewed in the Commonwealth on and after January 1, 2027.*

1105 *E. The provisions of this section shall not apply to short-term travel, accident-only, or limited or specified*
1106 *disease policies; contracts designed for issuance to persons eligible for coverage under Title XVIII of the*
1107 *Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental*
1108 *plans; or short-term nonrenewable policies of not more than six months' duration.*

1109 *F. The Commission shall not use any special fund revenues dedicated to its other functions and duties,*
1110 *including revenues from utility consumer taxes or fees from licensees regulated by the Commission or fees*
1111 *paid to the office of the clerk of the Commission, to fund the defrayal of costs for the coverage provided*
1112 *pursuant to subsection A as required by 42 U.S.C. § 18031 or any successor provisions thereof. The*
1113 *Commission shall not pay any funds beyond the moneys appropriated for the defrayal of costs related to such*
1114 *coverage. Appropriated funds remaining at year end shall not revert to the general fund but shall remain*
1115 *with the Commission for defrayal of costs related to such coverage.*

1116 *G. The limitation on cost-sharing required pursuant to this section shall only apply to a high deductible*
1117 *health plan, as defined in 26 U.S.C. § 223(c)(2), after the minimum deductible required under 26 U.S.C. §*
1118 *223(c)(2)(A)(i) has been satisfied, unless the required benefits have been determined to be preventative care*
1119 *under 26 U.S.C. § 223(c)(2)(C).*

1120 **§ 38.2-4319. Statutory construction and relationship to other laws.**

1121 *A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter,*
1122 *§§ 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,*
1123 *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,*
1124 *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*
1125 *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.), §*
1126 *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 (§*
1127 *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 (§*
1128 *38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, Chapter 15 (§ 38.2-1500 et seq.), Chapter 17 (§*
1129 *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,*
1130 *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,*
1131 *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,*
1132 *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.)*

1133 of Chapter 34, § 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1,
1134 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,
1135 and 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 35.1 (§ 38.2-3556 et seq.), §
1136 38.2-3610, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et
1137 seq.), Chapter 65 (§ 38.2-6500 et seq.), and Chapter 66 (§ 38.2-6600 et seq.) shall be applicable to any health
1138 maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or
1139 health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§
1140 38.2-4200 et seq.) except with respect to the activities of its health maintenance organization.

1141 B. For plans administered by the Department of Medical Assistance Services that provide benefits
1142 pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except
1143 this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200,
1144 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,
1145 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,
1146 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 (§
1147 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 (§
1148 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 (§
1149 38.2-1400 et seq.), 2 (§ 38.2-1412 et seq.), and 4 (§ 38.2-1446 et seq.) of Chapter 14, §§ 38.2-3401,
1150 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
1151 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,
1152 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,
1153 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
1154 § 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,
1155 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 (§
1156 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.), Chapter 65 (§ 38.2-6500 et seq.), and Chapter 66 (§
1157 38.2-6600 et seq.) shall be applicable to any health maintenance organization granted a license under this
1158 chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in
1159 conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) except with respect to the activities
1160 of its health maintenance organization.

1161 C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall

1162 not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

1163 D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice
1164 of medicine. All health care providers associated with a health maintenance organization shall be subject to
1165 all provisions of law.

1166 E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health
1167 maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer
1168 coverage to or accept applications from an employee who does not reside within the health maintenance
1169 organization's service area.

1170 F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B
1171 shall be construed to mean and include "health maintenance organizations" unless the section cited clearly
1172 applies to health maintenance organizations without such construction.

1173 **2. That the provisions of this act shall become effective on July 1, 2026, provided that the State Board**
1174 **of Health has promulgated regulations for the licensure of donor human milk banks as required by §**
1175 **32.1-162.15:15 of the Code of Virginia, as created by this act.**

1176 **3. That the provisions of this act may result in a net increase in periods of imprisonment or**
1177 **commitment. Pursuant to § 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary**
1178 **appropriation cannot be determined for periods of imprisonment in state adult correctional facilities;**
1179 **therefore, Chapter 2 of the Acts of Assembly of 2024, Special Session I, requires the Virginia Criminal**
1180 **Sentencing Commission to assign a minimum fiscal impact of \$50,000. Pursuant to § 30-19.1:4 of the**
1181 **Code of Virginia, the estimated amount of the necessary appropriation cannot be determined for**
1182 **periods of commitment to the custody of the Department of Juvenile Justice.**