SENATE BILL NO. 413
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Commerce and Labor
on _____)
(Patron Prior to Substitute—Senator Peake)

A BILL to amend and reenact §§ 2.2-2818, 38.2-3465, 38.2-3466, 38.2-3467, and 38.2-3470 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 2.2-2818.3, relating to health insurance; state health plan; pharmacy benefits managers; civil penalty.

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-2818, 38.2-3465, 38.2-3466, 38.2-3467, and 38.2-3470 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 2.2-2818.3 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 procedure that shall provide resolution within time frames established by federal law. For appeals involving adverse decisions as defined in § 32.1-137.7, the Department shall contract with one or more independent

review organizations to review such decisions. Independent review organizations are entities that conduct independent external review of adverse benefit determinations. The Department shall adopt regulations to assure that the independent review organization conducting the reviews has adequate standards, credentials and experience for such review. The independent review organization shall examine the final denial of claims to determine whether the decision is objective, clinically valid, and compatible with established principles of health care. The decision of the independent review organization shall (i) be in writing, (ii) contain findings of fact as to the material issues in the case and the basis for those findings, and (iii) be final and binding if consistent with law and policy.

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

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

For persons previously covered under the plan, there shall be no denial of coverage due to the existence of

a preexisting condition. The cost of early intervention services shall not be applied to any contractual provision limiting the total amount of coverage paid by the insurer to or on behalf of the insured during the insured's lifetime.

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

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

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

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

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

10. Include coverage for annual pap smears, including coverage, on and after July 1, 1999, for annual 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 prostate-specific antigen test in a 12-month period and digital rectal examinations.

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 the visit.

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

except when the provider is terminated for cause.

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

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

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

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

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

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

For purposes of this subdivision:

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

Community Clinical Oncology Program.

"FDA" means the Federal Food and Drug Administration.

"Multiple project assurance contract" means a contract between an institution and the federal Department of Health and Human Services that defines the relationship of the institution to the federal Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

"NCI" means the National Cancer Institute.

"NIH" means the National Institutes of Health.

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

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

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

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

a. The National Cancer Institute;

b. An NCI cooperative group or an NCI center;

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

d. The federal Department of Veterans Affairs; or

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

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

Coverage under this subdivision shall apply only if:

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

(2) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at

least as effective as the noninvestigational alternative; and

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

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

17. Include coverage for biologically based mental illness.

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

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

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

18. Offer and make available coverage for the treatment of morbid obesity through gastric bypass surgery or such other methods as may be recognized by the National Institutes of Health as effective for the long-term reversal of morbid obesity. Such coverage shall have durational limits, dollar limits, deductibles, copayments,

and coinsurance factors that are no less favorable than for physical illness generally. Access to surgery for morbid obesity shall not be restricted based upon dietary or any other criteria not approved by the National Institutes of Health. For purposes of this subdivision, "morbid obesity" means (i) a weight that is at least 100 pounds over or twice the ideal weight for frame, age, height, and gender as specified in the 1983 Metropolitan Life Insurance tables, (ii) a body mass index (BMI) equal to or greater than 35 kilograms per meter squared with comorbidity or coexisting medical conditions such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes, or (iii) a BMI of 40 kilograms per meter squared without such comorbidity. As used herein, "BMI" equals weight in kilograms divided by height in meters squared.

19. Include coverage 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. The coverage for colorectal cancer screening shall not be more restrictive than or separate from coverage provided for any other illness, condition, or disorder for purposes of determining deductibles, benefit year or lifetime durational limits, benefit year or lifetime dollar limits, lifetime episodes or treatment limits, copayment and coinsurance factors, and benefit year maximum for deductibles and copayments and coinsurance factors.

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

21. Include coverage 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 coverage shall include follow-up audiological examinations as recommended by a physician, a physician assistant, an advanced practice registered nurse, or an audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss.

22. Notwithstanding any provision of this section to the contrary, every plan established in accordance

with this section shall comply with the provisions of ~~§~~ *§§* 2.2-2818.2 *and 2.2-2818.3*.

C. Claims incurred during a fiscal year but not reported during that fiscal year shall be paid from such funds as shall be appropriated by law. Appropriations, premiums, and other payments shall be deposited in the employee health insurance fund, from which payments for claims, premiums, cost containment programs, and administrative expenses shall be withdrawn from time to time. The funds of the health insurance fund shall be deemed separate and independent trust funds, shall be segregated from all other funds of the 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 by unrelated entities. No later than July 1, 2006, one of the health coverage options to be available in each planning district shall be a high deductible health plan that would qualify for a health savings account pursuant to § 223 of the Internal Revenue Code of 1986, as amended.

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

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

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

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

Any plan established in accordance with this section shall be authorized to provide for the selection of a single mail order pharmacy provider as the exclusive provider of pharmacy services that are delivered to the

covered person's address by mail, common carrier, or delivery service. As used in this subsection, "mail order pharmacy provider" means a pharmacy permitted to conduct business in the Commonwealth whose primary business is to dispense a prescription drug or device under a prescriptive drug order and to deliver the drug or device to a patient primarily by mail, common carrier, or delivery service.

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

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

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

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

The Ombudsman shall:

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

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

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

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

5. Make available, either separately or through an existing Internet web site utilized by the Department of Human Resource Management, information as set forth in subdivision 4 and such additional information as he deems appropriate.

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

7. Upon request, assist covered employees in using the procedures and processes available to them from

their health plan, including all appeal procedures. Such assistance may require the review of health care records of a covered employee, which shall be done only in accordance with the federal Health Insurance Portability and Accountability Act privacy rules. The confidentiality of any such medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

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

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

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

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

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

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

P. Any plan established by the Department of Human Resource Management pursuant to this section shall provide that coverage under such plan for family members enrolled under a participating state employee's

coverage shall continue for a period of at least 30 days following the death of such state employee.

Q. The plan established in accordance with this section that follows a policy of sending its payment to the covered employee or covered family member for a claim for services received from a nonparticipating physician or osteopath shall (i) include language in the member handbook that notifies the covered employee of the responsibility to apply the plan payment to the claim from such nonparticipating provider, (ii) include this language with any such payment sent to the covered employee or covered family member, and (iii) 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.

§ 2.2-2818.3. Additional requirements for state employee health insurance plan.

A. As used in this section:

"Affiliate" means an entity, including a pharmacy, that directly or indirectly through one or more intermediaries (i) owns, in whole or in part, or controls a pharmacy benefits manager; (ii) is owned, in whole or in part, or controlled by a pharmacy benefits manager; or (iii) is a subsidiary of or owned, in whole or in part, or controlled by an entity that owns or controls a pharmacy benefits manager.

"In-network pharmacy" means a pharmacy licensed in the state in which such pharmacy is located that fills or seeks to fill a prescription for a beneficiary and is not barred from participating in the plan pursuant

to subsection E.

"Plan" means the plan established by the Department of Human Resource Management pursuant to this section.

"Pharmacy benefits management" means the managing or administration of a plan that pays for, reimburses, or covers the cost of prescription drugs and medical devices and includes the processing and payment of claims for prescription drugs and the adjudication of related appeals or grievances.

"Pharmacy benefits manager" means a person, affiliate, or other entity that performs pharmacy benefits management.

"Prescription drug" means a prescription drug covered by a health benefits plan that is dispensed to a beneficiary for self-administration.

"Rebate" means a payment or concession that accrues directly or indirectly to a pharmacy benefits manager or plan sponsor client of such pharmacy benefits manager, including through an off-shore entity or group purchasing organization, from a pharmaceutical manufacturer or its affiliate, subsidiary, intermediary, or third party, including payments, discounts, administration fees, credits, incentives, or penalties associated with claims administered by such pharmacy benefits manager on behalf of the plan.

B. The plan shall:

1. Require any pharmacy benefits manager administering prescription drug benefits on behalf of such plan, either directly or through an affiliate, to:

a. Reimburse an in-network pharmacy for the ingredient cost of a prescription drug in an amount equal to the sum of (i) the national average drug acquisition cost listed on the National Average Drug Acquisition Cost Index maintained by the U.S. Centers for Medicare and Medicaid Services for the drug on the date of claim adjudication or, if such drug does not appear on such index, the wholesale acquisition cost of such drug and (ii) the lesser of four percent of the amount described in clause (i) or $50;

b. Pay an in-network pharmacy a professional dispensing fee equal to the professional dispensing fee required to be paid by the state in which the pharmacy is located pursuant to Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.) for dispensing such drug; and

c. For any manufacturer rebate such pharmacy benefits manager or affiliate thereof receives in connection with a drug obtained at an in-network pharmacy by an individual pursuant to such prescription drug benefits, (i) apply at the point of sale a reduction to the amount of any coinsurance or copayment owed by such individual with respect to such drug such that the amount of such coinsurance or copayment is calculated based on the net cost of the drug, including such rebate, and (ii) remit to the carrier for the plan

the difference between the amount of such rebate and the amount by which such coinsurance or copayment is reduced;

2. Prohibit any pharmacy benefits manager described in subdivision 1 from:

a. Directing, ordering, or requiring an individual enrolled in the plan to use a specific pharmacy, including a pharmacy affiliated with such pharmacy benefits manager, for the purpose of filling a prescription or receiving services;

b. Advertising, marketing, or promoting a specific pharmacy, including a pharmacy affiliated with such pharmacy benefits manager, over another in-network pharmacy;

c. Creating any network or engaging in any practice, including the imposition of accreditation or credentialing standards, day supply limitations, or delivery method limitations, that excludes an in-network pharmacy or restricts such a pharmacy from filling a prescription for a drug for which benefits are available under the plan;

d. Directly or indirectly engaging in any practice that attempts to influence or induce a pharmaceutical manufacturer to limit the distribution of a prescription drug to specific pharmacies or to restrict such distribution to non-affiliate pharmacies;

e. Requiring an individual enrolled in the plan to reimburse the pharmacy benefits manager or its affiliate for the dispensing fee paid to an in-network pharmacy pursuant to subdivision 1 b with respect to a prescription drug dispensed by such pharmacy to such individual or otherwise increasing the amount owed by such individual with respect to such drug to account for such dispensing fee; or

f. Reducing, imposing a fee on, or otherwise adjusting a prescription drug claim at the time such claim is adjudicated or thereafter in a manner that reduces the amount a pharmacy is reimbursed for such drug pursuant to subdivision 1, including by charging a fee to such pharmacy that is not associated with a prescription drug claim.

3. Require the carrier of the plan to cooperate with any inspection by the Department pursuant to subsection C, including by making available such documents, personnel, and facilities as necessary to carry out such inspection.

C. Except as otherwise provided in this section, if the Department of Human Resource Management determines that a pharmacy benefits manager has violated a requirement or prohibition applicable to such pharmacy benefits manager with respect to the plan, the Department shall, in consultation with the Office of the Attorney General, impose a civil monetary penalty of $10,000 for each such violation on such pharmacy benefits manager. If five civil penalties are imposed pursuant to this subsection within a period of 10 years,

the Department shall also impose a civil monetary penalty of $10,000 for each subsequent violation within such period on the carrier of the plan. Within 60 days after the imposition of any such penalty on a carrier, such carrier shall develop and submit to the Department a plan to ensure that each pharmacy benefits manager administering prescription drug benefits on behalf of the plan complies with the requirements of this section. After such plan is submitted, the Department shall conduct periodic inspections to assess such carrier's compliance with such plan. No such civil penalty shall be imposed for a violation that occurs six or more years before such imposition.

D. The Attorney General may initiate a civil action in a court of competent jurisdiction to enforce the provisions of this section. Any amount recovered pursuant to this subsection and any civil penalty collected pursuant to subsection C shall be paid to the Department for deposit into the Employees Health Benefits Fund.

E. No pharmacy benefits manager shall administer prescription drug benefits on behalf of the plan if the Department imposes civil penalties on such pharmacy benefits manager for ten or more violations of this section pursuant to subsection C within a 10-year period.

F. A pharmacy benefits manager that the Department determines has violated any provision of this section may appeal such determination, including reasonable notice and opportunity to request a hearing on the record and judicial review in accordance with such procedures as prescribed by the Department.

§ 38.2-3465. Definitions.

A. As used in this article, unless the context requires a different meaning:

"Affiliate" means an entity, including a pharmacy, that directly or indirectly through one or more intermediaries (i) owns, in whole or in part, or controls a pharmacy benefits manager; (ii) is owned, in whole or in part, or controlled by a pharmacy benefits manager; or (iii) is a subsidiary of or owned, in whole or in part, or controlled by an entity that owns or controls a pharmacy benefits manager.

"Aggregate retained rebate percentage" means the sum total dollar amount of a pharmacy benefits manager's retained rebates relating to all carrier clients of such pharmacy benefits manager divided by the sum total dollar amount of all rebates received by such pharmacy benefits manager relating to all such clients.

"Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15. However, "carrier" does not include a nonprofit health maintenance organization that operates as a group model whose internal pharmacy operation exclusively serves the members or patients of the nonprofit health maintenance organization.

"Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of administering,

filling, or refilling a prescription for a drug or for providing a medical supply or device.

"Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include (i) receiving payments for pharmacist services, (ii) making payments to pharmacists or pharmacies for pharmacist services, or (iii) both receiving and making payments.

"Contract pharmacy" means a pharmacy operating under contract with a 340B-covered entity to provide dispensing services to the 340B-covered entity, as described in 75 Fed. Reg. 10272 (March 5, 2010) or any superseding guidance published thereafter.

"Covered entity" means an entity described in § 340B(a)(4) of the federal Public Health Service Act, 42 U.S.C. § 256B(a)(4).

"Covered individual" means an individual receiving prescription medication coverage or reimbursement provided by a pharmacy benefits manager or a carrier under a health benefit plan.

"Health benefit plan" has the same meaning ascribed thereto in § 38.2-3438.

"Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail or through electronic submissions and to dispense medication to covered individuals through the use of the United States mail or other common or contract carrier services and that provides any consultation with covered individuals electronically rather than face-to-face.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of covered individuals. "Pharmacy benefits management" does not include any service provided by a nonprofit health maintenance organization that operates as a group model provided that the service is furnished through the internal pharmacy operation exclusively serves the members or patients of the nonprofit health maintenance organization.

"Pharmacy benefits manager" or "PBM" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes an entity acting for a PBM in a contractual relationship in the performance of pharmacy benefits management for a carrier, nonprofit hospital, or third-party payor under a health program administered by the Commonwealth.

"Pharmacy benefits manager affiliate" means a business, pharmacy, or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership interest or control with a pharmacy benefits manager.

"Rebate" means a ~~discount or other price concession, including without limitation incentives, disbursements, and reasonable estimates of a volume-based discount, or a payment that is (i) based on utilization of a prescription drug and (ii) paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy~~ *payment or other price concession that accrues directly or indirectly to a pharmacy benefits manager or plan sponsor client of such pharmacy benefits manager, including through an off-shore entity or group purchasing organization, from a pharmaceutical manufacturer or its affiliate, subsidiary, intermediary, or third party, including payments, discounts, administration fees, credits, incentives, or penalties associated with claims administered by such pharmacy benefits manager on behalf of a health benefit plan.*

"Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and makes available face-to-face consultations between licensed pharmacists and persons to whom medications are dispensed.

"Retained rebate" means a rebate that is not passed on to a health benefit plan.

"Retained rebate percentage" means the sum total dollar amount of a pharmacy benefits manager's retained rebates relating to a health benefit plan divided by the sum total dollar amount of all rebates received by such pharmacy benefits manager relating to such health benefit plan.

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

§ 38.2-3466. License required to provide pharmacy benefits management services; requirements for a license, renewal, and revocation or suspension; civil penalty.

A. Unless otherwise covered by a license as a carrier, no person shall provide pharmacy benefits management services or otherwise act as a pharmacy benefits manager in the Commonwealth without first obtaining a license in a manner and in a form prescribed by the Commission *and contingent upon the conditions set forth in this article.*

B. Each applicant for a license as a pharmacy benefits manager shall make application to the Commission, in the form and containing the information listed in subsection C and any other information the Commission prescribes. The Commission may require any documents reasonably necessary to verify the information

contained in an application. Each applicant shall, at the time of applying for a license, pay a nonrefundable application processing fee in an amount and in a manner prescribed by the Commission. The fee shall be collected by the Commission and paid directly into the state treasury and credited to the "Bureau of Insurance Special Fund — State Corporation Commission" for the maintenance of the Bureau of Insurance as provided in subsection B of § 38.2-400.

C. An applicant for a license as a pharmacy benefits manager shall provide the Commission the following information:

1. The name, address, and telephone contact number of the pharmacy benefits manager;

2. The name and address of each person with management or control over the pharmacy benefits manager;

3. The name and address of each person with a beneficial ownership interest in the pharmacy benefits manager; and

4. If the pharmacy benefits manager registrant (i) is a partnership or other unincorporated association, a limited liability company, or a corporation and (ii) has five or more partners, members, or stockholders, the registrant shall specify its legal structure and the total number of its partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing 10 percent or more of the voting securities of any other person.

D. An applicant shall provide the Commissioner with a signed statement indicating that, to the best of its knowledge, no officer with management or control of the pharmacy benefits manager has been convicted of a felony or has violated any of the requirements of state law applicable to pharmacy benefits managers, or, if the applicant cannot provide such a statement, a signed statement describing the relevant conviction or violation.

E. Except where prohibited by state or federal law, by submitting an application for a license, the applicant shall be deemed to have appointed the clerk of the Commission as the agent for service of process on the applicant in any action or proceeding arising in the Commonwealth out of or in connection with the exercise of the license. Such appointment of the clerk of the Commission as agent for service of process shall be irrevocable during the period within which a cause of action against the applicant may arise out of transactions with respect to subjects of pharmacy benefits management in the Commonwealth. Service of process on the clerk of the Commission shall conform to the provisions of Chapter 8 (§ 38.2-800 et seq.).

F. Each applicant that has complied with the provisions of this article and Commission regulations is entitled to and shall receive a license in the form the Commission prescribes.

G. Each pharmacy benefits manager shall renew its license annually and shall, at the time of renewal, pay a renewal fee in an amount and in a manner prescribed by the Commission. The fee shall be collected by the Commission and paid directly into the state treasury and credited to the "Bureau of Insurance Special Fund — State Corporation Commission" for the maintenance of the Bureau of Insurance as provided in subsection B of § 38.2-400.

H. The Commission may refuse to issue or renew a license or may revoke or suspend a license if it finds that the applicant or license holder has not complied with the provisions of this article or Commission regulations.

I. A person that violates the provisions of this section may be subject to a civil penalty of $5,000 for each day on which such violation occurs. The Commission may adopt such rules or establish such guidelines as may be necessary to enforce the provisions of this section.

§ 38.2-3467. Prohibited conduct by carriers and pharmacy benefits managers.

A. No carrier on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager shall:

1. Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue;

2. Charge a pharmacist or pharmacy a fee related to the adjudication of a claim other than a reasonable fee for an initial claim submission;

3. Reimburse a pharmacy or pharmacist an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services, calculated on a per-unit basis using the same generic product identifier or generic code number and reflecting all drug manufacturer's rebates, direct and indirect administrative fees, and costs and any remuneration;

4. Penalize or retaliate against a pharmacist or pharmacy for exercising rights provided pursuant to the provisions of this article;

5. Impose requirements, exclusions, reimbursement terms, or other conditions on a covered entity or contract pharmacy that differ from those applied to entities or pharmacies that are not covered entities or contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or pharmacy dispenses 340B-covered drugs. Nothing in this subdivision shall (i) apply to drugs with an annual estimated per-patient cost exceeding $250,000 or (ii) prohibit the identification of a 340B reimbursement request; ~~or~~

6. Interfere with a covered individual's right to choose a pharmacy or provider, based on the pharmacy or provider's status as a covered entity or contract pharmacy*;*

7. Direct, order, or require an individual enrolled in the plan to use a specific pharmacy, including a pharmacy affiliated with such pharmacy benefits manager, for the purpose of filling a prescription or receiving services;

8. Advertise, market, or promote a specific pharmacy, including a pharmacy affiliated with such pharmacy benefits manager, over another in-network pharmacy;

9. Create any network or engage in any practice, including the imposition of accreditation or credentialing standards, day supply limitations, or delivery method limitations, that excludes an in-network pharmacy or restricts such a pharmacy from filling a prescription for a drug for which benefits are available under the plan;

10. Directly or indirectly engage in any practice that attempts to influence or induce a pharmaceutical manufacturer to limit the distribution of a prescription drug to specific pharmacies or to restrict such distribution to non-affiliate pharmacies;

11. Require an individual enrolled in the plan to reimburse the pharmacy benefits manager or its affiliate for the dispensing fee paid to an in-network pharmacy pursuant to subdivision F 2 with respect to a prescription drug dispensed by such pharmacy to such individual or otherwise increase the amount owed by such individual with respect to such drug to account for such dispensing fee; or

12. Reduce, impose a fee on, or otherwise adjust a prescription drug claim at the time such claim is adjudicated or thereafter in a manner that reduces the amount a pharmacy is reimbursed for such drug pursuant to subdivision 1, including by charging a fee to such pharmacy that is not associated with a prescription drug claim.

B. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall restrict participation of a pharmacy in a pharmacy network for provider accreditation standards or certification requirements if a pharmacist meets such accreditation standards or certification standards.

C. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall include any mail order pharmacy or pharmacy benefits manager affiliate in calculating or determining network adequacy under any law or contract in the Commonwealth.

D. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a

pharmacy benefits manager, shall conduct spread pricing in the Commonwealth.

E. Each carrier on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager shall comply with the provisions of this section in addition to complying with the provisions of § 38.2-3407.15:1.

F. Each pharmacy benefits manager shall:

1. Reimburse an in-network pharmacy for the ingredient cost of a prescription drug in an amount equal to the sum of (i) the national average drug acquisition cost listed on the National Average Drug Acquisition Cost Index maintained by the U.S. Centers for Medicare and Medicaid Services for the drug on the date of claim adjudication or, if such drug does not appear on such index, the wholesale acquisition cost of such drug and (ii) the lesser of four percent of the amount described in clause (i) or $50;

2. Pay an in-network pharmacy a professional dispensing fee equal to the professional dispensing fee required to be paid by the state in which the pharmacy is located pursuant to Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.) for dispensing such drug; and

3. For any manufacturer rebate such pharmacy benefits manager or affiliate thereof receives in connection with a drug obtained at an in-network pharmacy by an individual pursuant to such prescription drug benefits, (i) apply at the point of sale a reduction to the amount of any coinsurance or copayment owed by such individual with respect to such drug such that the amount of such coinsurance or copayment is calculated based on the net cost of the drug, including such rebate, and (ii) remit to the carrier for the plan the difference between the amount of such rebate and the amount by which such coinsurance or copayment is reduced.

§ 38.2-3470. Scope of article.

This article shall not apply with respect to claims under (i) an employee welfare benefit plan as defined in section 3 (1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1002(1), that is self-insured or self-funded~~;~~ *or* (ii) ~~coverages issued pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid); or (iii)~~ prescription drug coverages issued pursuant to Part D of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare Part D).