REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR CANCER TREATMENTS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 40

COMMONWEALTH OF VIRGINIA
RICHMOND
2000

COMMONWEALTH OF VIRGINIA

STEPHEN H. MARTIN
11TH SENATORIAL DISTRICT
PART OF CHESTERFIELD AND DINWIDDIE COUNTIES;
AMELIA COUNTY; CITY OF COLONIAL HEIGHTS;
POST OFFICE BOX 36147
RICHMOND, VIRGINIA 23235

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH
GENERAL LAWS
LOCAL GOVERNMENT
PRIVILEGES AND ELECTIONS

SENATE

January 13, 2000

To: The Honorable James S. Gilmore III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 9-298 and 9-299 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to assess the social and financial impact and the medical efficacy of 1999 Senate Bill 1281 regarding mandatory coverage for cancer treatments.

Respectfully submitted,

Stephen H. Martin
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

Stephen H. Martin, Chairman
James M. Shuler, Vice-Chairman

Thomas K. Norment, Jr.
Vivian E. Watts
Johanna B. Chase
R. DuVal Dickinson
Charles B. Garber
Dao Huynh
Matthew D. Jenkins
Stephen P. Long, M.D.
James F. McIntyre, III
Virginia Norton, Ph.D.
Fred M. Rankin, III
John L. Roper, IV
Alfred W. Gross
E. Anne Peterson, M.D., M.P.H.

TABLE OF CONTENTS

SECTION	PAGE
INTRODUCTION	1
SUMMARY OF PROPOSED LEGISLATION	1
CANCER TREATMENTS	2
SOCIAL IMPACT	4
FINANCIAL IMPACT	4
REVIEW OF CLAIMS DENIALS	4
INSURANCE COVERAGE	5
SIMILAR LEGISLATION IN OTHER STATES	5
REVIEW CRITERIA:	6
SOCIAL IMPACT	6
FINANCIAL IMPACT	7
MEDICAL EFFICACY	9
EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS	10
RECOMMENDATION	11
CONCLUSION	11
APPENDIX: A - 1999 SENATE BILL 1281	A-1

INTRODUCTION

The Senate Committee on Commerce and Labor referred Senate Bill 1281 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 1999 Session of the General Assembly. The patron of Senate Bill 1281 is Jane H. Woods.

The Advisory Commission held a hearing to receive public comments on the bill on June 30, 1999, in Richmond. In addition to the patron, two citizens and a representative of the American Cancer Society spoke in support of the bill. A representative of the Virginia Association of Health Plans (VAHP) spoke in opposition to the bill. Written comments in support of the bill were received from a private citizen. Written comments opposing the bill were received from the Health Insurance Association of America (HIAA), the VAHP, and the Virginia Manufacturers Association (VMA).

The Advisory Commission concluded its review of Senate Bill 1281 on November 22, 1999.

SUMMARY OF PROPOSED LEGISLATION

The bill amends Section 38.2-3407.5 in Title 38.2 of the Code of Virginia. The bill revises the provision prohibiting the denial of benefits for certain prescription drugs to include language providing that any policy, contract, plan or certificate, or evidence of coverage that includes coverage for "surgical procedures, radiation, other therapies or supportive care prescribed for the treatment of cancer" cannot deny coverage if the procedure, radiation therapy, or supportive care has been approved by the United States Food and Drug Administration (FDA) for use in the treatment of cancer on the basis that it has not been approved for the treatment of the specific type of cancer for which the surgical procedure, radiation, other therapy or supportive care has been prescribed if (i) the drug has been recognized as safe and effective for treatment of that specific type of cancer in any of the standard reference compendia or (ii) such drug, surgical procedure, radiation, other therapy or supportive care has been approved for clinical use for the treatment of cancer by one of the National Institutes of Health, regardless of whether approved by the FDA for the treatment of any disease or condition or for any cancer.

The bill applies to individual and group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, corporations providing individual or group accident and sickness subscription contracts, and health maintenance organizations (HMOs) providing health care plans.

The bill also amends § 2.1-20.1 of the Code of Virginia that addresses health coverage for state employees. The bill includes identical requirements and prohibitions for the health insurance coverage provided for state employees.

Senator Woods addressed the language in the bill at the June 30, 1999 meeting. She acknowledged that there were problems with the bill's language. The bill is intended to limit an insurer's ability to deny coverage solely because a treatment, procedure, or technique is being done in a slightly different way. The bill was described as not being intended to mandate a new benefit or procedure or to cover part of clinical trials. The treatments would not be denied as being experimental. Senator Woods asked for time to work with interested parties to develop substitute language that would then be submitted to the Advisory Commission.

CANCER TREATMENTS

Cancer is the abnormal growth, reproduction, and spread of body cells. The body contains trillions of cells. Most cells grow, reproduce, and die according to signals that are received from inside and outside the body. If the growth, reproduction, and death are balanced and orderly, the body will remain healthy.

When the cells mutate into cancer cells, there are problems. A normal cell can become a cancer cell for a reason that is not apparent or because of repeated or prolonged exposure to a cancer-causing (carcinogenic) substance such as tobacco or alcohol.

More than 100 different diseases are considered, or classified, as a type of cancer. Most cancers fall into one of three main groups: carcinomas, sarcomas, or leukemia and lymphoma. Carcinomas include cancers that begin from cells that form the skin, link internal organs, or form glands.

Sarcomas include cancers that originate from connective tissues such as bone and cartilage or from muscle tissues. Leukemia and lymphoma include cancers that originate from blood-forming cells and cells within the immune system.

In the past, a cancer diagnosis meant certain death. Modern medical treatment enables many cancer patients to live longer, healthier lives.

According to information from the Cancer Treatment Center of America, treatment for cancer has progressed rapidly in the past 30 years. Three main treatments are generally prescribed for cancer: surgery, radiation therapy,

chemotherapy, or a combination of the three. The type of treatment used depends on the cancer type, stage of progression, and the location of the cancer.

Surgery is usually advisable when the cancer can safely be removed from the body. Healthy tissue is left in place and only the cancerous portion of the tissue is removed. Sometimes when the cancerous cells have spread, surgeons must remove healthy tissue to ensure that the entire malignancy is removed. The physician removes lymph nodes from the tumor area because cancer can be spread through the nodes. If removing the lymph nodes does not eliminate the malignancy, physicians combine some surgical procedures with either chemotherapy or radiation therapy to kill any malignancy remaining after surgery.

Radiation can destroy cancer cells. Sometimes radiation therapy is provided by injecting radiation into the blood stream. When it circulates through the body, it finds cancer and destroys it. Another method involves implanting radioactive capsules directly into the tumor. The most common form of therapy is machine radiation where a small beam of radiation is focused at the tumor. The radiation kills the cells in the beam's focus. The radiation goes through the body without killing all the cells along its path. This is accomplished by rotating the machine and leaving it focused on the tumor long enough to be lethal. The healthy cells receive some radiation but not enough to be lethal.

Chemotherapy uses poison drugs that take advantage of cancer cells' rapid growth and heavy consumption of nutrients. Antimetabolites are a type of drug used and mimic the nutrients that are consumed by the body's cells. The drugs are injected into the bloodstream and are consumed by every cell. The cancerous cells consume more poisonous drugs than normal cells and the drugs then destroy the cancerous cells faster than normal cells.

Another type of chemotherapy drug interferes with the duplication of DNA and the cells cannot reproduce. A new type of drug, called monoclonal antibodies, is designed to affect only cancer cells and leave healthy cells undamaged.

The new area of treatment is biological therapy, using "biological" substances produced by the body's own cells and biological response modifiers to help the body fight cancer. The National Cancer Institute is also studying nutrients that are known as phytochemicals in foods, like fruits and vegetables. Researchers hope to manufacture the phytochemicals into cancer-fighting food or substances.

SOCIAL IMPACT

In 1995, at least 26,437 Virginians were diagnosed with some form of cancer, according to information reported to the Virginia Cancer Registry. The 1996 figures indicate that at least 27,320 Virginians were diagnosed with cancer. These figures reflect a conservative account of cancer in Virginia because not all hospitals, outpatient facilities, and private pathology laboratories were reporting cases to the registry over the time periods covered.

FINANCIAL IMPACT

Researchers, led by a Mayo Clinic oncologist, followed 61 patients who entered clinical trials of various treatments at the Mayo Clinic from 1988 to 1994. They were compared to 61 patients who had similar tumors who were eligible for clinical trials but chose standard therapy. The patients were followed for five years or until they died. Hospital, physician, and related service costs were estimated from a population-based cost database that was developed by Mayo Clinic staff. One of the study findings, reported in the Journal of the National Cancer Institute, was that the average total cost in 1995 inflation-adjusted dollars per patient in clinical trials was $46,424 and $44,133 for the patients receiving standard treatment. The report, "Incremental Cost of Enrolling Cancer Patients in Clinical Trials: a Population-Based Study," appeared in the May 19, 1999 issue of the Journal.

REVIEW OF CLAIMS DENIALS

Recent legislation enacted in Virginia (House Bill 871) requires the establishment of an external review process for adverse decisions by utilization review entities. The bill provides in §§ 38.2-5900 through 38.2-5902 of the Code of Virginia that a covered person or treating health care provider can appeal to the Bureau of Insurance. The health care services must cost more than $500 to be eligible for the review.

The Bureau of Insurance will conduct a preliminary review to determine whether the appeal meets the requirements of the statute. Appeals that comply with the requirements will be forwarded to an impartial entity to perform the review.

The external review process would be available to insureds after they have exhausted the complaint and appeals procedures under the policy and § 32.1-137.7.

The process will be effective July 1, 2000 or 90 days after the promulgation of regulations, whichever is sooner.

INSURANCE COVERAGE

The State Corporation Commission's Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia in March, 1999 regarding the bills to be reviewed by the Advisory Commission this year. Twenty-nine companies responded to the survey by April 9, 1999. Five of the companies indicated that they have little, if any, applicable health insurance business in force in Virginia. Of the 24 respondents that completed the survey, 13 indicated that they currently provide the coverage required by Senate Bill 1281. Eight companies do not provide the coverage in any contracts. One company provides some of the mandated coverage. One company includes the coverage in group contracts but not in individual contracts. Another company provides the coverage in individual contracts but not in group contracts.

SIMILAR LEGISLATION IN OTHER STATES

The Advisory Commission staff surveyed other state insurance departments and received information available from the National Association of Insurance Commissioners and the National Insurance Law Service to determine if requirements similar to Senate Bill 1281 are in effect in other states. According to the information we received, no states have legislation that is identical to Senate Bill 1281. There are states that have specific requirements for types of treatments or conditions.

The State of Georgia requires coverage for clinical trials for treatment of children's cancer. Michigan requires coverage for antineoplastic therapy drugs. Pennsylvania requires coverage for chemotherapy and hormone treatments. Kentucky and Louisiana require coverage for cancer drugs along with Maine, whose requirement is for the provision of off-label drugs. Minnesota requires coverage for diethylstil-bestrol-related (DES) cancer. Legislation was passed in Illinois (House Bill 1622) that would require the offer of the option of coverage for investigational cancer treatments. Rhode Island requires coverage for clinical trials for new cancer therapies. Maryland requires coverage for patients' costs for clinical trials as a result of treatment for a life-threatening condition, or prevention, early detection, and treatment studies on cancer. Similar legislation was proposed in Arizona but did not pass (Senate Bill 1165).

REVIEW CRITERIA

SOCIAL IMPACT

a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

At least 26,437 Virginians were diagnosed with some form of cancer in 1995. There were at least 27,320 Virginians diagnosed in 1996. The actual numbers may have been higher because all facilities were not reporting information to the Virginia Cancer Registry in those years.

b. *The extent to which insurance coverage for the treatment or service is already generally available.*

The State Corporation Commission's Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia in March, 1999. Twenty-four respondents completed the survey. Thirteen of the twenty-four companies (54%) indicated that they provide the coverage required by Senate Bill 1281. Eight companies do not provide the coverage in any contracts. One company provides some of the required benefits but not all. One company includes the coverage in group contracts but not individual contracts. Another company includes the coverage in individual contracts but not group contracts.

c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

At the public hearing, one person described his experience and the difficulty that he encountered because his request for treatment was denied. He had to wait until he was able to raise funding to obtain the treatment.

d. *If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

Public testimony from one proponent described having to obtain funds from charitable contributions because of the denial of coverage. The treatment requested by the insured required $100,000 before the care was rendered.

e. *The level of public demand for the treatment or service.*

The level of public demand is not known. The bill does not mandate a new treatment. Services are not requested until a diagnosis of a disease is made.

f. *The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.*

The written comments and testimony indicate support for the coverage required by Senate Bill 1281. It is difficult for insureds to understand why a treatment will be covered by their insurer before another procedure but not after the procedure. Proponents also described other patients receiving coverage from the same insurer for the treatment.

g. *The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts is not known.

h. *Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

No information or findings of the state health planning agency or the appropriate health system agency relating to the social impact or the mandated benefit.

FINANCIAL IMPACT

a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service other the next five years.*

Proponents make the argument that the bill does not propose a new benefit. They believe the bill requires coverage when a benefit that is already covered is provided in a slightly different manner.

b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

Proponents made the argument that the appropriate use of treatments would increase, while use of treatments covered, but sometimes not successful, would decrease.

The Virginia Association of Health Plans voiced concerns about patient safety and the risks associated with what could be inappropriate treatments.

Others who oppose the bill commented that the safety and quality of treatments could not be assured if there was no approval from any organization or in medical literature.

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

It is difficult to quantify the expense of a particular treatment or procedure for cancer. The information from the Mayo Clinic study of clinical trial patients indicated an average cost of $46,424 for patients in clinical trials and $44,133 for patients receiving standard care.

The exact cost of treatment will vary with the cost of drugs and other care for each patient. Patients' weight, other health conditions, stage, location, and type of cancers will all vary. The amount of drugs and other treatments will vary based on those and other factors.

d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

The bill is not expected to affect the number of providers of the treatments or services.

e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

Seven insurers supplied estimates on the premium cost of the bill on individual policies. The estimates ranged from $1.01 to $10 a month with one insurer estimating 1% to 3% of the premium. Twelve insurers provided estimates of the cost to add the coverage to group contracts. Their estimates ranged from

$0.00 to $4.64 a month. One insurer estimated less than 1% of premium and two others estimated $0.10 and $1.65 per member per month. A number of insurers commented that they were unsure of what would be covered and/or could not estimate the cost.

f. The impact of coverage on the total cost of health care.

Proponents argue that the impact of the requirement on the total cost of health care is not expected to be significant. The mandated care would be provided instead of the standard treatment that is already covered.

MEDICAL EFFICACY

a. The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.

Proponents of the bill believe that it is prudent to require this type of coverage because it will assist patients who need treatment and cannot wait to go through an appeals process with their insurer. They believe that recent medical advances should be recognized. They are not asking for coverage of a particular treatment.

Those who oppose the bill believe that, with the recent passage of legislation mandating coverage for clinical trials for cancer, this legislation is not necessary.

b. If the legislation seeks to mandate coverage of an additional class of practitioners:

1) The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.

Not applicable.

2) The methods of the appropriate professional organization that assure clinical proficiency.

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

The proposed mandate addresses a medical need. Proponents believe that it is consistent with the role of health insurance.

Opponents of the bill believe that it is not appropriate to require coverage for what is essentially a Phase 1 clinical trial.

b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

The need for immediate coverage is considered critical by proponents of the bill. Approximately 27,000 Virginians were diagnosed with cancer in 1995 and another 27,000 were diagnosed in 1996.

The Virginia Manufacturers Association believes that it is inappropriate for the General Assembly to substitute the political process for medical research. They believe that the language in the original bill would require coverage for a treatment, even if it had never been recognized as safe and effective by any organization, for the specific type of cancer being treated.

The VAHP believes the language could be interpreted as requiring coverage for treatments that may have never been tested on humans. The bill may require coverage for treatments that are not in the patient's best interest. The VAHP also believes that the recent legislation that requires an external review and appeals process (House Bill 871) will be able to address the original concerns about denial of coverage for cancer treatments.

c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

The cost of a mandated offer of coverage is anticipated to be higher because the cost would rest only on those who select the coverage. In the case of group insurance, the decision of whether to select the optional coverage would lie with the master contract holder and not the individual.

RECOMMENDATION

The Advisory Commission voted on Senate Bill 1281 on November 22, 1999. The Advisory Commission voted to recommend against the enactment of the bill, as it was originally proposed. The various interested parties were unable to develop language on which they could agree, and alternative language was not presented to the Advisory Commission.

The Advisory Commission recommended that policies, contracts, or plans be precluded from denying coverage for a specific drug, therapy, or procedure prescribed by a physician in the treatment of a type of cancer solely on the grounds that the FDA has not approved such drug, therapy, or procedure for use in treating such type of cancer, provided the prescribing physician reasonably believes such drug, therapy, or procedure is medically necessary and appropriate in the treatment of the patient.

CONCLUSION

The Advisory Commission believes that the original language of Senate Bill 1281 is broad and might require coverage beyond the original intent. The Advisory Commission also believes that the language could be limited to address the concerns that a cancer treatment should not be denied coverage solely on the basis that it lacks FDA approval for a particular type of cancer if, in the physician's determination, it is appropriate for the patient.

999038760

SENATE BILL NO. 1281

Offered January 21, 1999

A BILL to amend and reenact §§ 2.1-20.1 and 38.2-3407.5 of the Code of Virginia, relating to coverage of certain cancer treatments.

Patrons—Woods, Barry, Colgan, Miller, Y.B. and Puckett

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.1-20.1 and 38.2-3407.5 of the Code of Virginia are amended and reenacted as follows:

§ 2.1-20.1. Health and related insurance for state employees.

A. 1. The Governor shall establish a plan 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 Department of Personnel and Training shall administer this section. The plan chosen shall provide means whereby coverage for the families or dependents of state employees may be purchased. The Commonwealth may pay all or a portion of the cost thereof, and for such portion as the Commonwealth does not pay, the employee may purchase the coverage by paying the additional cost over the cost of coverage for an employee.

2. Such contribution shall be financed through appropriations provided by law.

B. The plan shall:

1. a. 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 thirty-five through thirty-nine, one such mammogram biennially to persons age forty through forty-nine, and one such mammogram annually to persons age fifty and over and may be limited to a benefit of fifty dollars 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.

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

(1) The mammogram must 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 physician, (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 must be sent or delivered to the health care practitioner who ordered it;

(2) 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

(3) 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 the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute. For persons previously covered under the plan, there shall be no denial of coverage due to the existence of a preexisting condition.

3. Include coverage for postpartum services providing inpatient care and a home visit or visits which 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.

4. Include an appeals process for resolution of written complaints concerning denials or partial denials of claims that shall provide reasonable procedures for resolution of such written complaints and shall be published and disseminated to all covered state employees. Such appeals process shall include a separate expedited emergency appeals procedure which shall provide resolution within one business day of receipt of a complaint concerning situations requiring immediate medical care.

5. 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 Mental Health, Mental Retardation, and Substance Abuse 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 Mental Health, Mental Retardation, and Substance Abuse 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 which 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.

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

7. Not deny coverage for any drug, *surgical procedure, radiation, other therapy or supportive care prescribed for the treatment of the cancer and* approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug, *surgical procedure, radiation, other therapy or supportive care* 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, *surgical procedure, radiation, other therapy or supportive care* has been prescribed, if *(i)* the drug, *surgical procedure, radiation, other therapy or supportive care* has been recognized as safe and effective for treatment of that specific type of cancer in one of the standard reference compendia *or (ii) such drug, surgical procedure, radiation, other therapy or supportive care has been approved for clinical use by one of the National Institutes of Health, regardless of whether approved by the United States Food and Drug Administration for the treatment of any disease or condition or for any cancer.*

8. 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.

9. 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 healthcare 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.

10. 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 may be no denial of coverage due to preexisting conditions.

11. Include coverage for annual pap smears.

12. Include coverage providing a minimum stay in the hospital of not less than forty-eight hours a patient following a radical or modified radical mastectomy and twenty-four 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.

13. Include coverage (i) to persons age fifty and over and (ii) to persons age forty 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 twelve-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.

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 beneficiaries thereof. 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 the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing Information.

"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 Medical College of Virginia Hospitals Authority as provided in § 23-50.16:24.

E. Provisions shall be made for retired employees to obtain coverage under the above plan. 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 Personnel and Training which 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.

§ 38.2-3407.5. Denial of benefits for certain prescription drugs and other treatments prohibited.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs, *surgical procedures, radiation, other therapies or supportive care prescribed for the treatment of cancer,* whether on an inpatient basis, outpatient basis, or both, shall provide in each such policy, contract, plan, certificate, and evidence of coverage that such benefits will not be denied for any drug, *surgical procedure, radiation, other therapy or supportive care prescribed for the treatment of cancer,* approved by the United States Food and Drug Administration for use in the treatment of cancer on the basis that the drug, *surgical procedure, radiation, other therapy or supportive care* 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,

surgical procedure, radiation, other therapy or supportive care has been prescribed, ~~provided~~*if (i)* the drug has been recognized as safe and effective for treatment of that specific type of cancer in any of the standard reference compendia *or (ii) such drug, surgical procedure, radiation, other therapy or supportive care has been approved for clinical use for the treatment of cancer by one of the National Institutes of Health, regardless of whether approved by the United States Food and Drug Administration for the treatment of any disease or condition or for any cancer.*

B. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs, whether on an inpatient basis, outpatient basis, or both, shall provide in each such policy, contract, plan, certificate, and evidence of coverage, that such benefits will not be denied 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.

C. For the purposes of subsections A and B:

"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 the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing Information.

D. Coverage, as described in subsections A and B, includes medically necessary services associated with the administration of the drug.

E. Subsections A and B shall not be construed to do any of the following:

1. Require coverage for any drug if the United States Food and Drug Administration has determined its use to be contraindicated for the treatment of the specific type of cancer or indication for which the drug has been prescribed;

2. Require coverage for experimental drugs not otherwise approved for any indication by the United States Food and Drug Administration;

3. Alter any law with regard to provisions limiting the coverage of drugs that have not been approved by the United States Food and Drug Administration;

4. Create, impair, alter, limit, modify, enlarge, abrogate, or prohibit reimbursement for drugs used in the treatment of any other disease or condition; or

5. Require coverage for prescription drugs in any contract, policy or plan that does not otherwise provide such coverage.

F. The provisions of this section shall not apply to short-term travel, or accident-only policies, or to short-term nonrenewable policies of not more than six months' duration.

G. The provisions of subsection A are applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1994, and the provisions of subsection B are applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1997.