REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

HOUSE BILL NO. 623: MANDATED COVERAGE FOR TREATMENT OF BRAIN TUMORS AT NATIONAL CANCER INSTITUTE CENTERS OF EXCELLENCE

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
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December 19, 2006

TO: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2.-2506 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 623 regarding a mandate of coverage for treatment of brain tumors at National Cancer Institute Centers of Excellence.

Respectfully submitted,

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INTRODUCTION

House Bill 623 was introduced in the 2006 Session of the General Assembly by Delegate John M. O'Bannon, III. The bill was referred to the Special Advisory Commission on Mandated Health Insurance (Advisory Commission) by the House Committee on Commerce and Labor.

The Advisory Commission held a public hearing in October 17, 2006 in Richmond to receive public comments on House Bill 623. Delegate John S. Reid introduced the bill. A representative of the Cullather Brain Tumor Quality of Life Center at St. Mary's Hospital (Cullather Center) and three concerned citizens spoke in favor 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 provided by the Cullather Center and a concerned citizen. Written comments in opposition to the bill were submitted by VAHP and the Virginia Chamber of Commerce (VCC).

The Joint Legislative Audit and Review Commission (JLARC) staff of the Virginia General Assembly prepared an "Evaluation of House Bill 623 Mandated Coverage for Treatment of Malignant Brain Tumors at NCCI Cancer Centers" pursuant to Sections 2.2-2503 and 30.58.1 of the Code of Virginia. A copy of the evaluation is available on the JLARC website at http://jlarc.state.va.us.

SUMMARY OF PROPOSED LEGISLATION

House Bill 623 would add Section 38.2-3418.15 to the Accident and Sickness Provisions Chapter of the Insurance Code and would amend Section 38.2-4319 in the Health Maintenance Organizations (HMOs) Chapter of the Insurance Code to make the provisions of the bill applicable to HMOs.

The bill applies to insurers that issue individual and group accident and sickness policies that provide hospital, medical and surgical coverage on an expense incurred basis, corporations providing individual or group accident and sickness subscription contracts, and each HMO providing health care plans for health care services. The bill requires that insurers, corporations, and HMOs provide coverage for treatment of a malignant brain tumor at a National Cancer Institute Center of Excellence within 300 miles of a patient's residence if the patient elects to have treatments performed at such a center and the treatment is otherwise covered.

The bill prohibits insurers, corporations and HMOs from imposing a copayment, fee, policy year or calendar year, or durational benefit limitation or maximum that is not equally imposed on all individuals in the same category. The bill applies to all policies, contracts and plans delivered, issued for delivery, reissued, or extended in Virginia on and after January 1, 2007, or anytime after

January 1, 2007 when there is a change in any term of the policy, contract or plan or any change is made in the premium.

The bill does not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, or policies or contracts designed for issuance to people eligible for Medicare, or any other similar coverage under state or federal plans.

Technical Concerns

The following technical concerns were identified in House Bill 623:

- The term "patient" is used rather than "insured", "enrollee" or "covered person" in subsection A of proposed § 38.2-3418.15.
- In Subsection A of § 38.2-3418.15, reference is made to the covered *patient's* election to receive treatment at a medical center designated by the National Cancer Institute as a "center of excellence" that is located within 300 miles of the patient's residence. The bill may have been intended to apply when the covered person's *physician* requested treatment at the center of excellence.
- Proponents of House Bill 623 originally indicated that the intent of the bill was to require coverage at NCI cancer centers.

Proposed Changes to House Bill 623

Written comments provided for the public hearing from proponents stated that the bill was intended to require coverage for treatment of primary brain tumors. Changes were suggested by the proponents that would require coverage for second opinions, and for Phase 1 and Phase 2 clinical trials otherwise covered by the policy, if the covered patient elects to have treatment performed at a NCI comprehensive cancer center located within 300 miles of the patient's residence.[i]

By a letter dated November 9, 2006, Delegate O'Bannon requested that the bill be revised to limit its scope. Delegate O'Bannon requested that the bill be changed to require coverage of a second opinion at a NCI comprehensive cancer center for primary malignant brain tumors. The revision would coverage for Phase III clinical trials and would allow insurers and HMOs to negotiate with the comprehensive centers for any ongoing treatment. Delegate O'Bannon stated at the November 20, 2006 meeting that the revisions would not mandate that a treatment regimen be covered after a second opinion was received.[ii]

NATIONAL CANCER INSTITUTE CANCER CENTERS

The National Cancer Institute is the principal agency of the federal government that addresses cancer research and training. NCI was the first institute of the National Institutes of Health and was established by Congress by the National Cancer Institute Act in August of 1937. The National Cancer Act of 1971 expanded the duties and scope of the agency to more effectively address the effort against cancer by the federal government.[iii]

The Cancer Centers program of NCI supports academic and research institutions in the country to create coordinated, interdisciplinary programs to conduct cancer research. The NCI considers the institutions in its program as demonstrating scientific excellence combined with the ability to coordinate diverse research approaches. Cancer Centers entering the program may be separate or free-standing, part of an academic institution or a consortium that has been formalized with central leadership. All types of centers must meet identical criteria to be accepted. The criteria address scientific, organizational and administrative requirements. [iv]

The NCI designates some facilities as cancer centers and others as comprehensive cancer centers. The cancer centers must conduct basic, population sciences, and clinical research. The centers are also encouraged to participate in collaborative research that addresses more than one field of study. Some of the centers do not provide patient care and conduct only laboratory research. Centers that provide patient care are expected to conduct innovative clinical trials in early stages of the disease. The centers also participate in the cooperative group program of the NCI. Comprehensive cancer centers must conduct research and provide care to patients. In addition to laboratory, clinical, behavioral and population-based research, and early phase innovative clinical trials, comprehensive centers must conduct outreach and education activities. The comprehensive centers must provide information to the public and to health care professionals.[v]

The NCI considers the following characteristics to be essential of an NCI-designated center:

Facilities dedicated to the conduct of cancer focused research, and to the center's shared resources, administration, and research dissemination should be appropriate and adequate to the task.

Organizational capabilities for the conduct of research and the evaluation and planning of center activities should take maximum advantage of the parent institution's capabilities in cancer research.

Interdisciplinary and Transdisciplinary Collaboration and Coordination: Substantial coordination, interaction, and collaboration among center members from a variety of disciplines should enhance and add value to the productivity and quality of research in the center.

Cancer Focus: A defined scientific focus on cancer research should be clear from the center members' grants and contracts, and from the structure and objectives of its programs.

Institutional Commitment: The center should be recognized as a formal organizational component with sufficient space, positions and resources to insure organizational stability and fulfill the center's objectives.

Center Director: The director should be a highly qualified scientist and administrator with leadership experience and institutional authority appropriate to manage the center.[vi]

There were 61 NCI cancer centers as of May, 2006. A complete list of the centers is located in Appendix B. The centers in Virginia and neighboring states include:

Lombardi Comprehensive Cancer Center
Georgetown University
Washington, D.C.

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Baltimore, MD

The Cancer Institute of New Jersey
New Brunswick, NJ

Albert Einstein Cancer Center
Albert Einstein College of Medicine
Bronx, NY

Herbert Irving Comprehensive Cancer
New York-Presbyterian Hospital
Columbia University Medical Center
New York, NY

Memorial Sloan-Kettering Cancer Center
New York, NY

The Cancer Institute of New Jersey
New Brunswick, NJ

Comprehensive Cancer Center of Wake Forest University
Wake Forest University Baptist Medical Center
Winston-Salem, NC

Duke Comprehensive Cancer Center
Duke University Medical Center
Durham, NC

UNC Lineberger Comprehensive Cancer Center
University of North Carolina Medical School
Chapel Hill, NC

St. Jude's Children's Research Hospital
Memphis, TN

The Vanderbilt-Ingram Cancer Center
Vanderbilt University
Nashville, TN

Massey Cancer Center
Virginia Commonwealth University
Richmond, VA

The Cancer Center at the University of Virginia
University of Virginia Health System
Charlottesville, VA[vii]

Treatments for brain tumors are also provided at the Surgery Branch of the NCI in Bethesda, Maryland. The surgery branch provides surgical consultative care and clinical care in many surgical subspecialties.[viii]

BACKGROUND INFORMATION

Brain Tumors

Brain (and spinal cord) tumors are abnormal growths of tissue that are found inside the skull or bony spinal column. Non-cancerous tumors are referred to as benign while cancerous tumors are classified as malignant. According to information from the National Institute of Neurological Disorders and Strokes of the National Institutes of Health, any abnormal growth in the brain and other components of the central nervous system can impair functions because the central nervous system is located in the skull and spinal column. The skull is rigid and there is little room for growth of a tumor. Tumors that begin in the brain are called primary tumors. The cause of most primary tumors is considerable growth among cells that surround and support neurons. [ix]

Many brain tumors actually begin in another location in the body and spread to the brain. The tumors that spread to the brain are called metastatic tumors. The common symptoms of brain tumors are frequent headaches, vomiting, loss of appetite, changes in mood and personality, changes in ability to think and learn, and seizures. A neurological examination is used to diagnose brain tumors. Computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography may be used to locate an adult brain tumor. A sample of the tissue from the tumor is removed surgically to assist with the diagnosis. [x]

The cause of most brain tumors is uncertain. Rare hereditary syndromes have been proven causes of the tumors in some individuals and the effects of therapeutic radiation and immumosuppression have been identified as causes in some other cases. Most research on the risk factors for cancer that begins in the brain has resulted in findings that are considered uncertain. [xi]

Treatments for Brain Tumors

Tumors that begin in the brain can spread to other parts of the central nervous system but usually do not spread to other organs. The great danger of brain tumors is the impact they have on normal functions of the brain. Significant factors that are considered in brain cancer treatment are:

- the type of cell
- how quickly it is spreading (grade)
- the patient's age; and
- the damage to brain function the tumor has caused.

The tumor's location and size are also factors in treatment decisions.[xii]

Tumors are graded on a system with four categories. Grade I tumors grow slowly and have cells that look like normal cells. Grade 1 tumors usually do not spread to other tissues. A grade I tumor may be successfully removed completely by surgery. Grade II tumors may spread to surrounding tissues. The tumors may grow into higher-grade tumors. Grade III tumors grow more quickly than grade II tumors. The grade III cells are very different from normal cells and will most often spread. Grade IV tumors grow rapidly and are the most difficult tumors to treat.[xiii]

Options for treatment of brain tumors in adults include surgical removal, radiation therapy, chemotherapy or a combination of the three. Other treatments may be available through participation in clinical trials. A clinical trial is a research study that is conducted to improve current treatments or to provide information about treatments that are new. Hyperthermia therapy is one of the newer treatments for brain cancer. Body tissue is exposed to very high

temperatures. The temperatures are used to damage and kill cancer cells or increase the effects of radiation or anticancer drugs on the cells. Another newer therapy uses the patient's immune system in treatment of the tumors. Substances that are made in a laboratory or by the body itself are used to increase, direct or restore the defenses that the body has naturally. This treatment is called biologic therapy, or biotherapy or immunotherapy.[xiv]

Bone marrow transplantation and gene therapy are also potential treatments for brain tumors. The transplant program at St. Jude's Research Hospital lists high-risk brain tumors among the malignant diseases that may be treated by bone marrow transplants.[xv] The National Brain Tumor Foundation discusses the use of gene therapy as an experimental treatment for brain tumors.[xvi]

Some patients receive complementary and alternative medicine treatments. These therapies are based on the holistic approach to wellness. According to the American Brain Tumor Association, many physicians are not informed by their patients that they use these treatments. [xvii]The National Brain Tumor Foundation lists the following treatment options for children: surgery, shunting, radiation therapy, and chemotherapy.[xviii]

The National Comprehensive Cancer Network (NCCN) oncology guidelines address surgery and radiation therapy in the treatment of brain tumors. The NCCN radiation guidelines note brachytherpy, stereotactic fractionated radiotherapy, stereotactic radiosurgery, Intensity Modulated Radiation Therapy (IMRT), and protons as highly conformal radiation therapy used in brain tumor treatment.[xix]

Surgery

Surgeons try to move the entire tumor when it is possible to do so without damaging other brain tissue. In the event that critical brain tissue will be damaged, the surgeon will remove as much of the tumor that can be done safely. Removal of part of the tumor will usually relieve some of the symptoms because the pressure in the brain will be reduced. Sometimes no part of the tumor can be removed. The surgeon performs a biopsy and a very small piece of the tumor is removed so that the piece of the tumor can be examined. The biopsy may be done with a needle. [xx]

Radiation Therapy

Radiation therapy is also referred to as radiotherapy. Radiotherapy uses very high-powered rays to damage cancer cells and stop their growth. It is often used on tumors or parts of tumors that cannot be removed surgically or to kill remaining cancer cells. [xxi]

Radiation therapy is often provided in two ways. External radiation is radiation that comes from a machine. It is typically given five or less days a week for a number of weeks. The actual schedule will be determined by the size, type, and age of the patient. Implant radiation therapy is performed by placing radioactive material inside the tumor. The implant can be left in the brain for a short period of time or permanently. The patient will remain in the hospital a number of days while the implant's level of radioactivity is highest. The level of radioactivity will decrease over time.

Stereotactic radiosurgery is a type of radiation treatment. After the location of a tumor is determined, very high-energy rays are aimed at the tumor from many angles. The treatment is given in one heavy dose. The dose can reach the tumor and not damage the surrounding tissue. [xxii] Stereotactic fractionated radiotherapy is radiosurgery that is received over a period of time rather than in one large dose or in a one-day session. [xxiii]

Brachytherapy is sometimes referred to as seed implantation and is often an outpatient procedure. The seeds are placed inside the cancerous tissue.[xxiv]Intensity Modulated Radiation Therapy is a type of high-precision radiotherapy that uses computer-controlled x-ray accelerators to aim precise doses of radiation at cancerous tumors, or parts of tumors. The dose conforms to the three-dimensional shape of the tumor by modulating (controlling) the intensity of the beam of radiation. This focuses the radiation on the tumor and spares the surrounding tissue. [xxv] In proton treatment, the protons are "energized to specific velocities". The energies determine how deeply the maximum energy will be deposited in the body. The maximum energy is then deposited in the designated cancer volume and the healthy tissues around the cancer cells receive less injury. [xxvi]

Chemotherapy

Chemotherapy uses drugs to kill cancerous cells. A single drug may be used or drugs may be used in combination. The drugs may be given orally or they can be injected into a muscle or a blood vessel. After a period of receiving treatments there is a recovery period. Many drugs can be administered in a physician's office or the outpatient clinic of a hospital and the patient will not need to stay in a hospital overnight. But, based on the type of drugs, method of administration, and patient's health, a hospital stay may be required. [xxvii]

Complementary and Alternative Medicine

Complementary and alternative medicine is grouped in five categories described by the National Center for Complementary and Alternative Medicine. Alternative medical systems, mind-body interventions, biologically-based therapies, manipulative and body-based methods, and energy therapies are used by some patients as alternatives or in addition to conventional medical

treatments. Complementary and alternative medicine is used by some individuals in efforts to relieve pain, deal with side effects of treatments, or to reduce anxiety. [xxviii]

Clinical Trials

Clinical trials are research studies. They are an organized way to test a new treatment to determine if it is safe and effective. Patients in clinical trials volunteer for treatments that would not be available to them without the clinical trial. Results of clinical trials are compared to the best treatment that is known for an illness or condition. There must be some potential for the success of the treatment based on the results of laboratory experience, animal trials or previous clinical trials. [xxix]

Clinical trials are also used to study a different way to use a standard treatment. A trial might be done to learn how the treatment works on a particular group, children for example, that has not utilized the treatment before. [xxx]

The U.S. Food and Drug Administration (FDA) must approve each new drug or device before it can be sold. Manufacturers and distributors of drugs or devices must submit reports to the FDA to show the safety and effectiveness of the drugs or devices they plan to market. Clinical trials are the main way to provide proof of the effectiveness and safety of a product. [xxxi]

Researchers, physicians, and other health care professionals must follow the rules set by the FDA when they administer clinical trials. The FDA has requirements to protect people who agree to participate in the trials. Researchers are required to develop eligibility criteria that may include the age, sex, type of disease, stage of disease, previous treatments, or other medical conditions of the participants. The criteria remove medical variations that could complicate the study results. Clinical trials can be sponsored by a federal agency like the NCI or the Veterans Administration, a pharmaceutical company, or a health care provider or physician. The sponsor determines where the trial is located. Trials are usually run at medical centers, clinics, universities, or hospitals, and research sites. [xxxii]

The procedures in a clinical trial will be reviewed by an Institutional Review Board comprised of five or more members including scientists, doctors and lay people. The board must approve every trial in an assigned area. The board ensures that the necessary procedures are followed to protect the participants. The board will not approve a trial if it believes the research is of too great a risk to the potential participants. The board will also review the selection of participants and where the trial will be held. The review board also reviews the informed consent document for compliance with federal requirements and to make sure it is understandable for participants.[xxxiii]

SOCIAL IMPACT

The American Cancer Society's "Cancer Facts and Figures 2006", contains estimates for new cancers diagnosed and cancer deaths nationally and by state. New cases of cancer in the brain and other parts of the central nervous system are estimated to total 18,820. Deaths during 2006 from brain and nervous system cancers are estimated to number 12,820 nationwide. Deaths in Virginia in 2006 due to brain and central nervous system cancers are estimated to be 270.

The five-year relative survival rate for all cancers diagnosed from 1995 to 2001 increased to 65%. The national five-year survival rate for brain cancer was 33% for the years 1995-2001.[xxxiv]

Information on the occurrence of brain cancer in Virginia was obtained from the Virginia Cancer Registry in the Virginia Department of Health. Brain cancer rates and counts for 2001 through 2003 appear below:

	Count	Rate
2001	323	5.1
2002	343	4.8
2003	425	5.8

The total malignancy rate for 2001-2003 was 1,091 with an incidence rate of 5.1 per 100,000.

The Virginia Cancer Registry notes that the data it receives may be under-reported and that the figures it provides are conservative. The under-reporting is due in part to the fact that, at the present time, all hospitals, outpatient facilities and private pathology laboratories do not report cases to the Virginia Cancer Registry. [xxxv]

FINANCIAL IMPACT

Information was obtained from Virginia Health Information regarding the hospital costs associated with a primary or secondary diagnosis of Internal Classification of Diseases Codes 191.0 through 191.9, (malignant neoplasm of the brain). The hospital costs include all charges association with hospital stay. The average total charge was supplied for 68 facilities. The average charges ranged from $1,334 to $105,766. [xxxvi]

A 1999 study published in the Journal of the National Cancer Institute, "Incremental Costs of Enrolling Cancer Patients in Clinical Trials: a Population-Based Study", found that clinical trial enrollees incurred costs that were no more than 10% higher than patients that were not in trials. The five-year cost, in inflation-adjusted dollars, for patients in trials, was $46,424. The five-year cost for patients not in trials was $44,133. The one-year cost was $24,645 for clinical trial patients and $23,964 for patients not in trials.[xxxvii]

Another study published in the Journal of the National Cancer Institute in 2000, "Cost of Care for Patients in Cancer Clinical Trials", found that the one-year cost for enrollees in clinical trials was $17,003 for the patients in trials and $15,516 for the other patients. [xxxviii]

MEDICAL EFFICACY

As previously noted, the type of treatment for brain cancer is determined by a number of factors. The factors include the type and size of tumor, location, grade and the patient's medical condition. A summary of treatment options by the type of tumor retrieved from the NCI website on May 9, 2006 is found in Appendix C.

The efficacy of each treatment may differ, however without any treatment brain cancer is almost always fatal. Practice guidelines for existing treatments for brain cancer are discussed below and selected study findings are also included here. Cancer treatments continue to evolve. A search for clinical trials for brain cancer found at least eight clinical trials at VCU's Massey Cancer Center. Proponents of the bill indicated no clinical trials for primary brain tumors are currently available at VCU. At least twenty-three clinical trials for brain cancer were noted on at the NIH Clinical Cancer Center in Bethesda, Maryland and at least twenty-seven clinical trials country-wide were listed by the Musella Foundation for Brain Tumor Research and Information, Inc. The efficacy of clinical trials is addressed by the Institutional Review Board process required by the FDA as previously discussed. [xxxix] [xl] [xli]

The NCCN, an alliance of twenty of the leading cancer centers, seeks to improve the quality and effectiveness of care for cancer patients. NCCN created clinical practice guidelines for patients, clinicians, and health care decision makers. NCCN's guidelines in oncology are the standard for clinical policy. The guidelines are based on evaluation of scientific data and expert judgment by expert physicians from the NCCN's member institutions. The guidelines are updated on a continuous basis and cover more than 97% of all cancers. According to the NCCN, the guidelines are the most widely used in the treatment of cancer by oncologists. [xlii]

A study on NCI cancer centers, published in February 2005 compared patients who received treatment at NCI cancer centers to those who received treatment at hospitals that treat a high volume of cancer patients. The authors of the study examined the rates of surgical mortality and the survival rates for 63,860 patients. The patients were elderly and received care for lung, esophageal, gastric, pancreatic, bladder, or colon cancer. The study results indicated the patients survived colon, lung, gastric and esophageal surgery performed at NCI centers at significantly higher rates. A higher survival rate was also found for bladder and pancreatic cancer surgery but not as pronounced. The difference in the five-year survival rate was not significant (no more than 4%) for any of the procedures. [xliii]

NCI noted that the study did not address the stage of the cancer for the patients that were treated or the racial differences of the study participants. Both factors would impact the study results. [xliv]

A study published in the Journal of American Medical Association in 2002 titled "Patterns of Care for Adults with Newly Diagnosed Malignant Glioma" analyzed information from 565 adults with gliomas from 1997 to 2000. Information was obtained from questionnaires given to patients and their physicians. The patients were treated at 52 different facilities. The study findings indicated that only 87% of the patients received postoperative radiation therapy recommended by the practice guidelines in place at the time. While 32% of the patients had seizures, 89% of them were receiving anticonvulsants even though the guidelines recommend them only when the patient has seizures. Only 54% of the patients received chemotherapy, and only 15% received heparin after surgery to combat venous thromboembolism. The rate of participation in clinical trials was only 15% and almost 30% of the patients were using alternative medical treatments. [xlv]

CURRENT INSURANCE COVERAGE

Survey

The Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia regarding the three bills referred to the Advisory Commission for review in 2006. Forty-three companies responded to the survey by September 12, 2006. Eight of the respondents wrote little or no business applicable to House Bill 623. Completed surveys indicated that eighteen of the companies provided the coverage required by House Bill 623. However, seven of those responses were either qualified by additional statements in the survey response or qualified or reversed in follow-up communications. Sixteen of the companies responded that they do not provide the coverage required by the bill. One company did not respond regarding House Bill 623.

Of the fourteen Virginia licensed HMOs surveyed, twelve provided responses by September 12, 2006. Additional questions were asked of the twelve respondents regarding the inclusion of the University of Virginia Health System (UVA) or Virginia Commonwealth University (VCU) in their network of facilities. VCU is included in the network of six of the HMOs and UVA is included in the network of three HMOs. One respondent indicated that both VCU and UVA will be added to its network in the future. One HMO did not respond to the question by September 22, 2006. At least eight of the twelve HMOs respondents will have at least one NCI cancer center in their network with the additions made by the previously mentioned HMO.

Five companies provided cost figures ranging from $.55 to $1.08 per month to provide the coverage required by House Bill 623 in individual contracts. Four respondents estimated costs from $1.39 to $3.00 per month to provide the coverage on an optional basis. Twenty companies provided cost figures ranging from $.00 to $3.20 per month to include the coverage required by the bill in group contracts. The range of estimates from fourteen companies providing the coverage on an optional basis in group policies was from $.00 to $70.22 per month. One company provided only the monthly premium of $431.25 for a contract and did not provide premium attributable to the individual proposals.

Current Insurance Requirements Related to House Bill 623

Clinical Trials for Cancer

Section 38.2-3418.8 of the Code of Virginia requires insurers that issue individual or group accident and sickness policies that provide hospital, medical and surgical, or major medical coverage on an expense incurred basis; corporations providing individual or group subscription contracts; and HMOs providing health care plans to provide coverage for patient costs that are incurred during participation in clinical trials for treatment studies on cancer. The coverage must include coverage for ovarian cancer trials. This requirement became effective on July 1, 1999.

The coverage must include patient costs for Phase II, Phase III, and Phase IV clinical trials. Coverage must be provided for Phase I trials on a case-by-case basis. The coverage must be provided only if there is no clearly superior, non-investigational treatment alternative; the available clinical or preclinical data provides a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and the member and physician or health care provider who provides services to the member under the policy, contract or plan decide that the member's participation in the trial would be appropriate, pursuant to the procedures established by the insurer, corporation, or HMO.

Off-Label Prescription Drug Use

Section 38.2-3407.5 of the Code of Virginia provides that insurers issuing individual or 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 HMOs providing health care plans, who have a policy, contract, plan, or evidence of coverage that include coverage for prescription drugs cannot deny coverage for a prescription drug that is approved by the FDA for use in the treatment of cancer on the basis that the drug has not been approved for the treatment of the specific type of cancer for which the drug has been prescribed. The drug must be recognized as safe and effective for the treatment of the type of cancer it is prescribed for in any of the standard reference compendia. This provision applies to contracts issued after July 1, 1994.

Section 38.2-3407.5 of the Code of Virginia also provides that coverage cannot be denied for any drug prescribed to treat a covered indication as long as the drug has been approved by the FDA 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. This provision applies to contracts issued after July 1, 1997.

The section does not require coverage for experimental drugs not otherwise approved for any indication by the FDA or coverage for any drug if the FDA has determined that its use is contraindicated for the treatment of the type of cancer or indication for which the drug has been prescribed.

Point-of-Service Option

Section 38.2-3407.12 of the Code of Virginia requires HMOs and insurers offering coverage under indemnity contracts through preferred provider organizations (PPO), to offer a point of service benefit to enrollees under their health plans. The benefit must be offered to the individuals covered if they are covered under a group contract. The point of service benefit allows an enrollee and his dependents to receive covered benefits outside of the provider panel of the HMO or PPO. The requirement applies to plans issued or renewed in Virginia after July 1, 1998.

The Office of the Managed Care Ombudsman

The Office of the Managed Care Ombudsman was created in the Bureau of Insurance as a result of legislation enacted in 1998. The Ombudsman's office works with enrollees and insureds that are covered by managed care health insurance plans (MCHIPs) that are offered by HMOs and PPOs. Individuals covered by MCHIPs have the right to appeal a decision about treatment or coverage. The Ombudsman's office was created to assist consumers in

understanding and exercising their rights of appeal of decisions that are made by MCHIPs. The Ombudsman's office helps consumers as they utilize the internal appeals and grievance process of their MCHIP.

Managed Care Health Insurance Plans External Appeals

In 1999, legislation was enacted that requires an external appeals process for denials of coverage based on contracts issued in Virginia by MCHIPs. Unless the patient believes there is an emergency, the process is available to patients who have exhausted all internal appeals of the MCHIP. An appeal can be requested on an expedited basis if the patient believes that he has an emergency medical condition.

Patients may request a review if their MCHIP has denied coverage for care that the company determined was not medically necessary or involved experimental or investigative procedures.

INSURANCE MANDATES IN OTHER STATES

Information from the National Association of Insurance Commissioners (NAIC) was reviewed to determine whether other states have requirements similar to House Bill 623. Similar requirements were not found in any other states. However, Illinois requires the offer of coverage for experimental cancer treatments when an insured has terminal condition related to cancer. Florida has a requirement for coverage of chemotherapy in connection with bone marrow transplants. Vermont requires coverage for medically necessary growth cell stimulation factor injection as part of chemotherapy treatments. North Carolina and Missouri require coverage for participation in clinical trials.

Thirty-two states, including Virginia, require coverage for off-label drug use. Eleven states have some type of requirement for coverage of transplants. Nine of the eleven transplant requirements are for bone-marrow transplants for breast cancer. The other two states are Illinois and Rhode Island. Illinois prohibits HMOs from denying reimbursement on the basis that a transplant is considered experimental or investigational. Rhode Island requires that insurers cover new cancer therapies while they are under investigation if certain guidelines are met. [xlvi]

Review Criteria

SOCIAL IMPACT

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

Information from the Virginia Cancer Registry indicates there were at least 1,091 cases of malignant brain tumors in Virginia in the three-year period of 2001-2003. The incidence rate for the three-year period was 5.1 per 100,000. The Virginia Cancer Registry notes that the data it receives may be under-reported and that the figures are conservative.[xlvii]

The American Cancer Society's "Cancer Facts and Figures 2006" contains estimates on death rates for certain cancers for each state. The estimate of deaths in Virginia in 2006 due to brain and central nervous system cancers is 270.[xlviii]

The JLARC assessment estimated that 5,018 Virginians were diagnosed with a brain tumor in 2005 based on prevalence information from NCI.[xlix]

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

Coverage for treatment of brain tumors is provided under insurance policies and HMO plans. Coverage for treatment at NCI comprehensive cancer centers and NCI cancer centers is available to individuals with indemnity coverage. Virginians in HMO plans do not have NCI comprehensive cancer centers in their network. Two NCI cancer centers are located in Virginia. At least one of the two cancer centers is included in the networks of eight of twelve of the HMOs that responded to surveys and follow-up questions from the Bureau of Insurance. Treatment may also be available at NCI comprehensive centers to HMO enrollees through appeal processes.

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.

Coverage is available, but the lack of coverage for treatment at NCI comprehensive cancer centers for every Virginia is desired by proponents of the bill. Proponents of the bill testified at the public hearing as to the difficulties they faced in their attempts to obtain treatment at a NCI comprehensive cancer center in North Carolina. There was considerable discussion of the limited availability of clinical trials in Virginia for patients with primary brain tumors.[l]

The VAHP noted at the public hearing that coverage for clinical trials for cancer treatments is already mandated in Section 38.2-3418.8 of the Code of Virginia.[li]

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 treatments.

Information on the cost of care for clinical trials patients was obtained from to studies published in the Journal of the National Cancer Institute. A 1999 study found that the five-year treatment cost for patients in clinical trials and those not in clinical trials was $46,424 and $44,133, respectively. The one-year costs were $24,645 and $23,964 respectively.[lii]

Paying out-of-pocket for care that could range in cost from $15,000 to $46,000, based on costs in the 1999 and 2000 studies, could result in financial hardship for many families.

Proponents noted that the average person with a malignant brain tumor is a 55 year old male, and the occurrence of a brain tumor therefore usually impacts the family "bread winner" and economically devastates a family. They noted in written comments that people diagnosed with malignant brain tumors usually do not return to work after the diagnosis. When individuals travel to obtain treatment at a NCI comprehensive cancer center they incur the travel and lodging costs in addition to the cost of treatment.[liii]

The JLARC assessment included the average cost for treatment of metastatic brain tumors at one NCI cancer center of approximately $42,000. The same center reported average costs for high-grade and low-grade primary tumors as $27,000 and $16,000, respectively.

These average costs do not include laboratory tests or some treatments that may be received from providers.[liv]

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

Three concerned citizens spoke at the public hearing in support of the proposed mandate. They described the difficulties they encountered obtaining treatment at a NCI comprehensive cancer center. Proponents noted that at a time when a family member is fighting brain cancer obtaining permission to go receive care from a comprehensive cancer center can require a great deal of time and add stress to an already stressed family. One proponent of the mandate stated that the Brain Tumor Center at Duke University is currently treating 345 Virginians. The type of insurance coverage utilized by those patients was not provided.[lv]

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 level of demand from providers for insurance coverage for treatment at NCI cancer centers, or comprehensive cancer centers is not known. Three citizens testified about the need for insurance coverage for brain tumors patients for treatment at a NCI comprehensive cancer center.

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

No information was provided to the Advisory Commission regarding collective bargaining organizations' interest in the proposed coverage.

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

No information was received on the findings of a state health planning agency or health system agency on the social impact of House Bill 623, with the exception of the information from the Virginia Cancer Registry regarding the number of cases of malignant brain tumors reported to the registry in the three-year period 2001-2003 (1,091 reported malignancies).

Financial Impact

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

The VAHP believes that the proposed mandate could increase the cost of treatment for brain tumors. The original language of the bill was viewed as diminishing the incentive of a health care facility to negotiate the payment for services with a HMO or a PPO.[lvi] Supporters of the bill believe that because of the low number of patients diagnosed with primary brain tumors, and the number of those patients that would seek treatment at a NCI comprehensive cancer center, the financial impact of the proposed legislation on treatment cost would not be significant.

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

The inappropriate treatment of Virginians at a NCI comprehensive cancer center or cancer center is not expected to increase because patients would not receive services from a NCI center unless they were in need of the care as evidenced by their medical condition. Appropriate treatment would increase but

not in large numbers because approximately 400 Virginians develop malignant brain tumors each year.

The JLARC assessment estimated that as many as 828 patients with HMO coverage could use NCI centers as a result of the proposed legislation.[lvii]

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

With the exception of access to clinical trials, the actual treatments and services that would be provided to patients would not differ from the treatments that are currently available. Information from a 1999 study, "Incremental costs of Enrolling Cancer Patients in Clinical Trials: A Population Based Study" found that clinical trial enrollees costs of treatment were no more than 10% higher than the costs for patients that were not taking part in clinical trials.[lviii]

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 coverage of treatment of brain tumors at NCI cancer centers, or comprehensive cancer centers, is not expected to increase the number of centers in the next five years. The requirements for receiving the designations of NCI cancer center or NCI comprehensive cancer center are considerable and are not expected to be greatly impacted by an increase of insured patients of up to 400 per year.

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.*

Responses to the 2006 survey by the Bureau of Insurance provided some information on the estimated cost of the proposed mandate. Five companies provided cost figures ranging from $.55 to $1.08 per month to provide the coverage required by House Bill 623 in individual contracts. Four respondents estimated costs from $1.39 to $3.00 per month to provide the coverage individual contracts on an optional basis. Twenty companies provided cost figures ranging from $.00 to $3.20 per month to include the coverage required by the bill in group contracts. The range of estimates for providing the coverage on an optional basis in group policies was from $.00 to $70.22 per month with fourteen responses.

A limited increase in the administrative expenses of insurance companies and policyholders may occur as a result of revisions to the design of a policy, forms filing, claims processing systems and marketing costs.

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

The proposed mandate is expected to have a limited impact on the total cost of health care. The number of people with malignant brain tumors in Virginia is relatively low. Additionally, those Virginians insured under indemnity contracts, or managed care contracts that have requested the point-of service option already have access to comprehensive cancer centers and cancer centers. For those patients enrolled in clinical trials, at least two studies found an increase in treatment costs of approximately 10%.[lix]

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.

A study on NCI cancer centers, published in February, 2005 compared patients who received treatment at NCI cancer centers to those who received treatment at hospitals that treat a high volume of cancer patients. The rates of surgical mortality and survival rates were examined. The patients were elderly and received care for lung, esophageal, gastric, pancreatic, bladder, or colon cancer. The study results indicated the patients survived colon, lung, gastric and esophageal surgery performed at NCI centers at significantly higher rates. A higher survival rate was also found for bladder and pancreatic cancer surgery, but not pronounced. The difference in the five-year survival rate was not significant (no more than 4%) for any of the procedures. NCI noted that the study did not address the stage of the cancer for the patients or racial differences. The NCI stated that both of those factors would impact the study results.[lx]

The medical efficacy of clinical trials for cancer is addressed in the Institutional Review Board process as required by the FDA.[lxi]

Proponents of House Bill 623 noted studies by P. H. Coluzzi et al., "Survey of the Provision of Supportive Care Services at National Cancer Institute- Designated Cancer Centers", and R. W. Frelick et al, "The Community Clinical Oncology (CCOP) Program Story: Review of Community Oncologists' Experience with Clinical Research Trials in Cancer with an Emphasis on CCOP of the National Cancer Institute between 1982 and 1987" that establish that cancer patients treated at designated comprehensive cancer centers have a "significant survival advantage." The proponents also noted studies by S. Davis, R. Lenhard, and D. Nathan as supporting the efficacy of treatment at NCI cancer centers.[lxii]

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 to 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.

Proponents believe that House Bill 623 meets "broad medical and social needs with minimal costs". The proponents noted in written comments that "while the care at current Virginia cancer centers may meet standards for "necessary care", they do not offer sufficient treatments to provide a survival advantage". The proponents believe that because of the deadly nature of brain cancer, Virginians need access to NCI comprehensive cancer centers because they offer "cutting edge treatments." The proponents commented on the number of clinical trials for brain tumors and experimental treatments, and more variety in treatments available at NCI cancer centers in Virginia.[lxiii]

The JLARC evaluation of House Bill 623 found that the proposal was not consistent with the role of health insurance because "it would not fill a critical need for helping patients finance necessary health care costs." The assessment noted that health insurance provides coverage for treatments for malignant brain tumors and found that there was no compelling need for the proposed mandate. Many patients already have access to facilities that perform high volume brain surgeries.[lxiv]

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

Proponents noted in written comments that the costs of treatments would be low because of the low volume of patients with brain tumors. They also asserted every patient with a brain tumor would not seek treatment at a NCI comprehensive cancer center and therefore the cost impact of the proposal would be low.[lxv]

The VAHP believes that House Bill 623 could set precedence and other providers could request coverage for enrollees who go outside their network. The VAHP believes that the bill could defeat the purpose of networks that are "designed on the premise that volume equals discount". The VAHP notes that without networks insurance costs will increase and more individuals will be uninsured as a result. The VAHP also noted that UVA and VCU Health System are two NCI cancer centers in Virginia and most services for malignant brain tumors can be provided in Virginia.[lxvi]

In written comments, the VCC noted a June, 2006 report by JLARC that recognized that mandates can increase the cost of health care. The VCC also noted an October 2006 report to the Joint Commission on Health Care that showed a continued decline in employers offering health insurance. The VCC believes that additional mandated benefits will add to the cost of health coverage and employers will "rethink" how or if they will provide coverage to their employees and the dependents of the employees.[lxvii]

The JLARC assessment of House Bill 623 found that the need for the bill does not appear to outweigh the cost. The assessment determined the primary need for the bill was to provide additional access for those individuals with HMO coverage without a NCI cancer center in their network. (The patron clarified the original intent of the bill to require coverage at NCI cancer centers after the JLARC assessment was completed.) Insurers could pay approximately 10% more for treatment for a small number of patients resulting in some increase in the total cost of health care.[lxviii]

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

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insured. Proponents noted that when an individual insured is purchasing a policy or contract he does not anticipate developing a brain tumor. It is unlikely therefore that many individuals would purchase coverage for treatment at a NCI cancer center or NCI comprehensive cancer center if it was offered on an optional basis.

The JLARC assessment of House Bill 623 noted that a mandated offer of coverage would not address the need for coverage because the proposal addresses a rare condition and most purchasers would not view more location options for treatment as a critical need.[lxix]

CONCLUSION

Delegate O'Bannon withdrew House Bill 623 and his suggested changes to the bill from Advisory Commission review after a second vote by the Advisory Commission.

The Advisory Commission initially voted on November 20, 2006 to recommend against the enactment of the original language of House Bill 623 Yes-8, No-3, 1 abstention. The Advisory Commission subsequently considered making no recommendation on the bill because the research that was conducted, presented, and reviewed addressed the original bill language. There was some concern that it was difficult to provide an informed recommendation on the revised language. A motion to make no recommendation on the bill was defeated by a vote of Yes-4, No-5, and 3 abstentions.

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[vii] NCI-Cancer Centers Program-Cancer Centers List, June 8, 2006, http://www3.cancer.gov/cancercenters/cancercenterslist.html.

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[xi] The Essential Guide to Brain Tumors, San Francisco, National Brain Tumor Foundation, 2004.

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