REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

# HOUSE BILL NO. 2156
# MANDATED COVERAGE FOR SECOND OPINION EVALUATIONS OF PRIMARY MALIGNANT BRAIN TUMORS AT NATIONAL CANCER INSTITUTE COMPREHENSIVE CANCER CENTERS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2008

January 4, 2008

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

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 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 2156 regarding second opinion evaluations for primary malignant brain tumors at National Cancer Institute Cancer Centers.

Respectfully submitted,

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R. Lee Ware, Jr.
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

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## INTRODUCTION

House Bill 2156 was introduced in the 2007 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 Benefits (Advisory Commission) by the House Committee on Commerce and Labor.

The Advisory Commission held a public hearing on July 18, 2007 in Richmond to receive public comments on House Bill 2156. Delegate O'Bannon and Delegate John S. Reid spoke in favor of the bill. Two concerned citizens also 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 received from the Cullather Brain Tumor Quality of Life Center at St. Mary's Hospital (Cullather Center), Delegate Paula J. Miller, and Dr. Michael Friedman, President and CEO of City of Hope National Medical Center. Written comments in opposition to the bill were submitted by VAHP.

The Joint Legislative Audit and Review Commission (JLARC) staff of the Virginia General Assembly prepared an "Evaluation of House Bill 2156: Mandated Coverage of Second Opinions for Primary Malignant Brain Tumor Patients at NCI Comprehensive 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 2156 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 to make the provisions applicable to HMOs.

The bill applies to insurers that issue individual or 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 HMOs providing health care plans for health care services. The bill requires that insurers, corporations, and HMOs provide coverage for a second opinion evaluation of a primary malignant brain tumor at a medical center designated by the National Cancer Institute (NCI) as a comprehensive cancer center.

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, 2008, or when there is a change in any term of the policy, contract or plan, or any change 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 Concern

One technical concern has been noted with the bill. Language on line 30 would exclude cancer policies from the requirements of the bill. The phrase "policies other than cancer policies" could be added before the word "or" to make the bill applicable to cancer policies.

## Background

The House Committee on Commerce and Labor referred House Bill 623 to the Advisory Commission during the 2006 Session of the General Assembly. House Bill 623 was introduced by Delegate John M. O'Bannon III. The Advisory Commission held a hearing on October 17, 2006 in Richmond to receive public comments on House Bill 623. A representative of Cullather Center and three concerned citizens spoke in favor of the bill. A representative of the VAHP spoke in opposition to the bill. Written comments in favor of the bill were provided by a representative of the Cullather Center and a concerned citizen. Written comments in opposition to the bill were submitted by VAHP and the Virginia Chamber of Commerce.

House Bill 623 would have added Section 38.2-3418.15 and amended Section 38.2-4319 in the Code of Virginia. The original language of the bill required that insurers, corporations, and HMOs provide coverage at a NCI Center of Excellence within 300 miles of a patient's residence if the patient

elects to have treatments performed at a center and the treatment is otherwise covered. The bill applied to insurers that issue individual or group accident and sickness policies that provide hospital, medical and surgical coverage on an expense incurred basis, corporations providing individual and group accident and sickness subscription contracts, and HMOs providing health care plans for health care services.

Delegate O'Bannon indicated, prior to the public hearing, that the language of the bill was intended to require coverage at NCI cancer centers. Written comments provided for the hearing from proponents stated that the bill was intended to require coverage for the treatment of primary malignant brain tumors. Changes in the bill language were suggested by the proponents that would require coverage for second opinions, and Phase I and Phase II 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.

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

The Advisory Commission voted 8 to 3 with one abstention against recommending the original bill language. The Advisory Commission considered making no recommendation to the General Assembly and the Senate and House Committees on Commerce and Labor because the research that was conducted, presented, and reviewed addressed the original bill language. Concern was expressed about the Advisory Commission's ability to provide an informed recommendation on the revised language offered by Delegate O'Bannon on November 20, 2006. A motion was made to make no recommendation on the bill, but it was defeated. Delegate O'Bannon withdrew the proposals from Advisory Commission review after the second vote.

**National Cancer Institute Cancer Centers and Comprehensive 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 pursuant to the National Cancer Institute Act in August of 1937. The National Cancer Act of 1971 expanded the duties and scope of the agency to address more effectively the effort against cancer by the federal government.[1]

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 centers, 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.[2]

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 addressing 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 and 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.[3]

The NCI considers the following characteristics to be essential for 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's 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.[4]

There were 22 NCI cancer centers and 39 comprehensive cancer centers as of May, 2007. No comprehensive cancer centers are located in Virginia at this time. There are two cancer centers in Virginia. The centers are located at the University of Virginia and Virginia Commonwealth University. The existing comprehensive cancer centers are:

Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania

Arizona Cancer Center
University of Arizona
Tucson, Arizona

Cancer Institute of New Jersey

Robert Wood Johnson Medical School
New Brunswick, New Jersey

Case Comprehensive Cancer Center
Case Western Reserve University
Cleveland, Ohio

Chao Family Comprehensive Cancer Center
University of California at Irvine
Orange, California

City of Hope National Medical Center
Beckman Research institute
Duarte, California

Dana-Farber/Harvard Cancer Center
Dana-Farber Cancer Institute
Boston, Massachusetts

Duke Comprehensive Cancer Center
Duke University Medical Center
Durham, North Carolina

Fox Chase Cancer Center
Philadelphia, Pennsylvania

Fred Hutchinson/University of Washington Cancer Consortium
Fred Hutchinson Cancer Research Center
Seattle, Washington

H. Lee Moffitt Cancer Center and Research Institute
University of South Florida
Tampa, Florida

Herbert Irving Comprehensive Cancer Center
Columbia University
New York, New York

Holden Comprehensive Cancer Center
The University of Iowa

Iowa City, Iowa

Jonsson Comprehensive Cancer Center
University of California Los Angeles
Los Angeles, California

The Barbara Ann Karmanos Cancer Institute
Wayne State University School of Medicine
Detroit, Michigan

Lombardi Comprehensive Cancer Center
Georgetown University
Washington, DC

Mayo Clinic Cancer Center
Mayo Clinic Rochester
Rochester, Minnesota

M.D. Anderson Cancer Clinic
University of Texas
Houston, Texas

Memorial Sloan-Kettering Cancer Center
New York, New York

Norris Cotton Cancer Center
The Ohio State University
Columbus, Ohio

Rebecca and John Moores UCSD Cancer Center
University of California, San Diego
La Jolla, California

Robert H. Lurie Comprehensive Cancer Center
Northwestern University
Chicago, Illinois

Roswell Park Cancer Institute
Buffalo, New York

Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University
Baltimore, Maryland

Siteman Cancer Center
Washington University School of Medicine
St. Louis, Missouri

UAB Comprehensive Cancer Center
University of Alabama at Birmingham
Birmingham, Alabama

UCSF Comprehensive Cancer Center and Cancer Research Institute
University of California San Francisco
San Francisco, California

UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina
University of Colorado Cancer Center
University of Colorado at Denver and Health Sciences Center
Aurora, Colorado

University of Michigan Comprehensive Cancer Center
University of Michigan
Ann Arbor, Michigan

University of Minnesota Cancer Center
Minneapolis, Minnesota

University of Pittsburgh Cancer Institute
Pittsburgh, Pennsylvania

USC/Norris Comprehensive Cancer Center
University of Southern California
Los Angeles, California

UW Paul P. Carbone Comprehensive Cancer Center
University of Wisconsin

Madison, Wisconsin

Vanderbilt-Ingram Cancer Center
Vanderbilt University
Nashville, Tennessee

Vermont Cancer Center
University of Vermont
Burlington, Vermont

Wake Forest Comprehensive Cancer Center
Wake Forest University
Winston-Salem, North Carolina

Yale Cancer Center
Yale University School of Medicine
New Haven, Connecticut [5]

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.

## BRAIN TUMORS

Primary brain tumors include any tumor that begins in the brain. A tumor is a mass of abnormal cells. The tumor can be confined to a small area or it can spread to other areas. A brain tumor can be malignant, cancerous or benign. The tumors can destroy brain cells directly, or they can damage cells by producing inflammation that can compress other parts of the brain. The compression can cause swelling and increase pressure inside of the skull.[6]

Brain tumors are classified based on the location, type of tissue, malignancy, and other factors. A primary brain tumor can begin in brain cells, the membranes around the brain, nerves, or glands. The cause of primary brain tumors is unknown. There are many types of tumors, and

many risk factors can contribute to the development of the tumors. Some inherited conditions increase the risk of brain tumors. [7]

The symptoms of a brain tumor depend on the location, size, and degree of invasion and swelling. The most common symptoms are headaches, seizures, weakness in one part of the body, and changes in mental functions. Symptoms may include vomiting, loss of memory and impaired judgment, double or decreased vision, hearing loss, speech difficulties, personality and behavior changes, lethargy, reduced alertness, or emotional instability. [8]

A number of tests can confirm the existence of a brain tumor and where it is located. Computed tomography (CT), magnetic resonance imaging (MRI), examination of tumor tissue after surgical removal or CT-guided biopsy, or examination of cerebral spinal fluid and electroencephalograms (EEGs) are options.[9]

## 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.[10]

Tumors are graded on a system with four categories. Grade I tumors grow slowly and have cells that look like normal cells. Grade I tumors usually do not spread to other tissues. Grade II tumors may spread to surrounding tissues. The tumors may grow into higher-grade 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. [11]

Options for the 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, biotherapy or immunotherapy.[12]

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.[13] The National Brain Tumor Foundation (NBTF) discusses the use of gene therapy as an experimental treatment for brain tumors. For children, the NBTF includes surgery, shunting, radiation therapy, and chemotherapy as treatment options.[14]

The National Comprehensive Cancer Network (NCCN) oncology guidelines address surgery and radiation therapy in the treatment of brain tumors. The NCCN radiation guidelines note brachytherapy, stereotactic fractionated radiotherapy, stereotactic radiosurgery, Intensity Modulated Radiation Therapy (IMRT), and protons as highly conformal radiation therapy used in brain tumor treatment.[15]

## Surgery

The usual treatment for the majority of brain tumors is surgery. The surgeon will remove as much of the tumor as possible. Removing part of a tumor will usually relieve some of the symptoms as pressure on the brain is reduced. If the tumor is in the brain stem or some other areas of the brain it may not be possible to remove it. Patients who are not candidates for surgery may receive radiation.[16]

## Radiation Therapy

Radiation therapy uses high-powered rays to damage cancer cells and stop their growth. Radiation is usually administered after surgery. There are a number of ways radiation therapy is administered. The radiation can be provided internally by implanting radioactive material in the patient that is left inside the brain for a short period of time or permanently. External radiation can be provided in a number of ways that are aimed at helping to protect healthy tissue.[17]

The radiation may be administered using fractionation where the therapy is given five days a week for a number of weeks. When hyperfractionation is used, the patient receives smaller doses of radiation two or three times a day instead of a large dose once a day. Stereotactic radiation therapy uses narrow beams of radiation and directs them at tumors from different angles. The physician uses a computer to decide on the amount of radiation used and the size and angle of the radiation beams. The therapy can be given in a single dose or over a period of time. Three-dimensional conformal radiation therapy uses a computer to create a three-dimensional image of the tumor. Multiple beams are aimed at the exact shape of the tumor. Proton beam radiation therapy uses protons instead of x-rays. The protons do not damage healthy tissue as they treat the cancerous tumor.[18]

## Chemotherapy

Chemotherapy uses drugs to kill cancer cells. The drugs may be administered orally or by injection. The drugs may be given in the hospital, at the physician's office, or at a hospital outpatient clinic. A hospital stay might be necessary depending on the type of drug, how it is administered, and the patient's health status. [19]

## Clinical Trials

Clinical trials are research studies that provide an organized way to test a new treatment to determine if it is safe and effective. The patients in trials volunteer to participate for treatments that would not be available to them otherwise. The results of clinical trials are compared to the best treatment that is known for an illness or condition. Some potential for

success must exist based on the results of laboratory experience, animal trials, or previous clinical trials. Clinical trials are also used to study different ways of using standard treatments.[20]

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 information 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 information on the effectiveness and safety of a product.[21]

Researchers, physicians, and other health care professionals must follow the rules set by the FDA for clinical trials. The FDA has requirements that protect people who agree to participate. 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. Clinical trials can be sponsored by a federal agency like the NCI or 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.[22]

The procedures in a clinical trial will be reviewed by an Institutional Review Board. The boards have five or more members and include scientists, doctors, and lay people. The review boards make sure that procedures are followed to protect the participants. The review board will not approve a trial if it believes there is too great a risk to the potential participants. The board also reviews the selection of participants and the informed consent documents they receive.[23]

## Second Opinion Evaluations

A second opinion is defined in the Encyclopedia of Surgery: A Guide for Patients and Caregivers as "the process of seeking an evaluation by another doctor or surgeon to confirm the diagnosis and treatment plan of a primary physician or to offer an alternative diagnosis and/or treatment approach." The purpose of a second opinion can be to fill an emotional need and establish the clinical need for surgery or clarify that surgery is not

needed. Some patients obtain second opinions to obtain additional information.[24]

Second opinion evaluations can be requested by physicians or patients themselves. Many facilities provide request forms on their internet websites. Others accept requests by telephone and arrange visits. Some physicians and groups do not require visits and will review existing medical records and make evaluations. There are many firms that specialize in providing second opinions.

The National Cancer Institute's website states in part:

> Once you receive your doctor's opinion about the diagnosis and treatment plan, you may want to get another doctor's advice before you begin treatment. This is known as getting a second opinion. You can do this by asking another specialist to review all of the materials related to your case. A second opinion can confirm or suggest modifications to your doctor's proposed treatment plan, provide reassurance that you have explored all of your options, and answer any questions you may have.

According to the website, second opinion evaluations are provided frequently, and most doctors are comfortable with their patients requesting the opinions.[25]

## SOCIAL IMPACT

The American Cancer Society's "Facts and Figures 2007" contains estimates for new cancers diagnosed, and cancer deaths nationally and for each state. New cases of cancer in the brain and other parts of the central nervous system are estimated to total 20,500. Deaths during 2007 from brain and nervous system cancers are estimated to number 12,740 nationwide. The estimate of deaths in Virginia in 2007 due to brain and central nervous system cancers is 280.[26]

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 2000 through 2004 appear below:

| Year | Count | Rate |
|---|---|---|
| 2000 | 385 | 5.6 |
| 2001 | 326 | 4.6 |
| 2002 | 347 | 4.8 |
| 2003 | 431 | 5.9 |
| 2004 | 441 | 5.9 |

The registry notes that the data reflects a conservative account of the disease in Virginia. All hospitals, outpatient facilities, and private pathology laboratories have not begun reporting to the registry and Virginians sometimes receive their diagnosis and treatments in other states. There is sometimes a lag in reporting from other states' cancer registries. The registry notes that the data should be used cautiously.[27]

Information on brain cancer patients and second opinions was requested from two NCI comprehensive cancer centers and two NCI cancer centers. Information was received from one NCI cancer center and the tumor registry at one comprehensive cancer center by June 26, 2007. The cancer center indicated that approximately 35 second opinions are provided per year for patients with primary brain tumors. Less than 200 patients with primary malignant brain tumors are seen annually by one of the center's neurologists. An estimated 1 to 2 percent of those patients obtain a second opinion from a comprehensive cancer center.[28]

Information from the tumor registry at Duke Comprehensive Cancer Center indicates that 482 patients with primary brain tumors were seen there for the first time in 2005. Thirty-nine Virginians were included in the total.[29]

Seven clinical trials for primary brain tumors are currently being conducted at one of the NCI cancer centers located in Virginia. Each year approximately 30% of the patients at that cancer center are offered

participation in clinical trials.[30] One website for the Duke Comprehensive Cancer Center listed 9 clinical trials for pediatric brain tumors and 23 clinical trials for adult brain tumors in June 2007.[31]

## FINANCIAL IMPACT

Information about the costs of second opinions required by House Bill 2156 was requested from a number of sources. Proponents of House Bill 2156 estimated the cost of second opinion evaluations to be approximately $600.[32] Information from one cancer center in Virginia estimated an average cost of less than $400 (for a patient that was self-referring and previous diagnostic tests were used for the opinion.) [33] Multiple visits may be necessary for the evaluation.

Information on claim payments made for second opinions for primary brain tumors for state employees was also requested for this bill review. Between 2004 and 2006, less than 300 employees were diagnosed with primary malignant brain tumors (as classified in three Current Procedure Terminology codes.) Approximately one-third of the employees received second opinion evaluations. The average claim payment was less than $200.[34]

Information from four HMOs operating in Virginia provided payment estimates for second opinion evaluations of primary brain tumors ranging from $166 to $300. One HMO provided an average payment of $260 for second opinions at comprehensive cancer centers. For the other three companies, the payment was the same for comprehensive cancer centers as other providers. One additional HMO indicated an average payment of $2,000.[35]

## MEDICAL EFFICACY

The American Brain Tumor Association (ABTA) website says that seeking a second opinion is one way to obtain additional information. The site notes that an opinion from a second qualified physician may assure the patient that the recommended treatment is the best available. The opinion can advise the patient of other options, or provide a different perspective or clearer understanding of the situation. The information does note that a

second opinion should not delay a procedure in an emergency. A second opinion is noted as "standard medical practice." The ABTA site mentions that many physicians will discuss current treatments and other options after reviewing medical records and conducting a telephone interview.[36]

The American Cancer Society website notes that a second opinion is one way to find out "if a suggested treatment is best for you." The information also notes that results of the tests already completed can be sent to the second doctor.[37]

The Central Brain Tumor Registry of the United States (CBTRUS), discusses second, third, and fourth opinions on its website. The CBTRUS notes that diagnosing brain tumors is complicated. It says second opinions should come from experts within specific areas. The CBTRUS states:

> It's estimated that as many as twenty-five percent of brain tumor patients will have their diagnosis changed upon further examination by a second, expert opinion, which can drastically change not only the prognosis, but the recommended treatment plan. If your primary physician is not familiar with the most current treatments or clinical trials available for patients with brain tumors, request that he/she consult with one of the many major brain tumor centers and arrange for you to obtain a second, expert opinion.[38]

Many proponents of second opinions reference the study on second opinions published in 1999 by the Department of Pathology at the Johns Hopkins Medical Institutions. "Mandatory Second Opinion Surgical Pathology at a Large Referral Hospital" discusses the findings from the review of second opinions for surgical pathology at Johns Hopkins. Cases were collected over a 21-month period from April 1995 to December 1996. Most of the cases involved a change between malignant and benign tumors or a significant change in tumor classification. The study reviewed 6,171 cases and the second surgical pathology changed the diagnosis in 1.4% of the cases (86). The study concluded "Second opinion surgical pathology can result in major therapeutic and prognostic modifications for patients sent to larger referral hospitals." The authors noted that the percentage of affected cases was not large, but that the rate of diagnosis discrepancies might have a substantial human and financial effect. The authors recommended the review of original histologic material before a major therapeutic endeavor.[39]

A recent study by researchers at the University of Michigan Comprehensive Cancer Center looked at 149 consecutive breast cancer patients. The patients had been referred to the University of Michigan's multidisciplinary breast tumor board for a second opinion. The study found that over 52% of the patients had one or more changes made in the recommendations for surgery. The study found that radiologists re-interpreted imaging results in 45% of patients. Tumor board pathologists interpreted test results differently in 29% of patients. The study appeared in the November, 2006 issue of "Cancer."[40]

A national survey was conducted on second opinions by Harris Interactive Inc. (Harris) for the Wall Street Journal in March of 2005. The survey obtained responses from 2,137 adults in the United States. Harris found that 29% of those surveyed said they themselves or a family member had received a second medical opinion in the past five years, and that 30% of the second opinions resulted in a different diagnosis and treatment or care.[41]

## Current Insurance Coverage

The Bureau of Insurance surveyed fifty of the top writers of accident and sickness insurance in Virginia regarding the five bills referred to the Advisory Commission for review in 2007. Thirty-three companies responded to the survey request by June 29, 2007. Forty companies responded by July 23, 2007. Nine of the respondents wrote little or no business applicable to House Bill 2156. Completed survey responses indicate that twenty-one of the thirty-one respondents provide the coverage required by the bill. Only four of the non-HMO respondents do not provide the coverage. Those four respondents offer only network coverage in Virginia.

Five companies provided cost estimates ranging from $.10 to $1.00 per month to provide the coverage required by House Bill 2156 in individual contracts. Four companies estimated the cost of providing the coverage on an optional basis for individual contracts. The responses ranged from $.21

to $3.00. Ten companies provided responses for standard group coverage that ranged from $.00 to $2.60 per month. Three companies provided estimates of $.20 per month to provide the coverage on an optional basis for group contracts. One company estimated a cost of $1.37 per month. One company provided the monthly premium for a standard contract and did not provide premium attributable to the individual bills.

An additional survey was mailed to the sixteen HMOs that write business in Virginia that would be subject to House Bill 2156. Eleven of the HMOs responded by July 29, 2007. None of the HMOs require a second opinion for brain tumors patients, but all of the respondents will pay for a second opinion when provided by a network provider. One of the HMOs will routinely pay for an out-of-network second opinion. The other ten respondents may pay for a second opinion at a NCI comprehensive cancer center under certain conditions, including when there is no in-network provider available, there is approval by the plans' Medical Director, or with an approved referral.

None of the HMOs surveyed provide coverage for second opinions at all of the NCI comprehensive cancer centers. However, four of the eleven respondents have at least one comprehensive cancer center in their network.

## Current Insurance Requirements Related to House Bill 2156

### Clinical Trials for Cancer

Section 38.2-3418.8 of the Code of Virginia requires insurers to provide coverage for patient costs that are incurred during participation in clinical trials for treatment studies on cancer. The bill applies to 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. 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.

## 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 (PPOs) 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 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

Legislation was also enacted in 1999 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, or has a condition that would be terminal without treatment.

Patients may request a review if their MCHIP has denied coverage for care that the company determined is not medically necessary or involves experimental or investigative services. The cost of the service must exceed $300. The preliminary review of a request sent to the Bureau of Insurance must be completed within ten working days of receipt of all information necessary to conduct the review. The Bureau of Insurance must notify the applicant and MCHIP within 5 working days if the appeal is accepted. All entities must provide all relevant information to the Bureau within 20 working days after a standard appeal is accepted or within two working days if an expedited appeal is accepted.

## Insurance Requirements in Other States

Information was reviewed from the National Association of Insurance Commissioners to determine whether other states have requirements similar to House Bill 2156. Information was also obtained from a survey to state insurance departments. No state was found to have a requirement similar to House Bill 2156. However, at least ten states have some type of requirement for coverage of second opinions.

California requires insurers to pay for a second surgical opinion by an appropriately qualified health care professional. An insurer may limit second opinions to network providers. If there is no appropriately qualified professional in the network, the insured can receive the opinion from an out-of-network provider. Indiana requires HMOs to allow an enrollee to obtain a second opinion from a participating provider if the enrollee requests a second opinion. Maryland requires coverage for a second opinion if it is required by a hospital utilization review program. New Hampshire requires utilization review entities and managed care companies to have written

procedures for second opinion programs. New Jersey requires insurers to pay for a second surgical opinion for elective procedures by eligible procedures in the insurer's second opinion program.

Oregon requires insurers that offer health benefit plans requiring a referral for specialty care services to allow an enrollee to obtain a second opinion from a network provider regarding the need for a referral. If a network provider is not available, the enrollee can obtain the second opinion from a non-network provider. Rhode Island requires insurers to make available benefits for a second surgical opinion for elective surgical procedures for individual policies. Washington requires that each carrier allow an enrollee, upon request, to have access to a second opinion from a participating provider. West Virginia has a requirement that HMOs must provide enrollees with access to a second opinion from a participating provider upon the enrollee's request.

New York requires health plans to pay for a second surgical opinion for a patient who thinks he may have cancer or has received a diagnosis of cancer. The patient must receive the second opinion from a network physician unless he obtains a referral from his attending physician. New York's requirement is the only state requirement located thus far that is limited to one illness or condition.

## 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 that, in the three-year period 2002-2004, there were reports of 1,219 cases of primary malignant brain tumors in Virginia. The incidence rates were 4.8, 5.9 and 5.9, respectively, for each of the three years. The registry notes that these figures are conservative. [42]

The American Cancer Society's "Facts and Figures 2007" contains estimates on death rates for certain cancer sites for each state. The estimate for 2007 in Virginia for brain and central nervous system cancers is 280.[43]

One Virginia cancer center estimates that 1 to 2 percent of the patients they treated for primary malignant brain tumors obtain a second opinion from a comprehensive cancer center. Information was requested from nearby comprehensive cancer centers on the number of Virginians receiving second opinions for malignant brain tumors but was not received.

The JLARC assessment also noted that data was not available on the proportion of patients obtaining a second opinion from a comprehensive cancer center, but indications are that the number is likely to be low based on information from UVA, VCU, the state employee health plan, and some comprehensive centers. [44]

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

Coverage for second opinions for brain tumors is generally available. Of the 31 respondents to a survey by the Bureau of Insurance, 21 respondents provide coverage for second opinions at comprehensive centers. Six of the respondents not providing the coverage were HMOs and the other four respondents provide only network coverage in Virginia.

A separate survey was mailed to the 16 HMOs currently writing full service coverage in Virginia. Eleven responded by July 9, 2007. All of the respondents will pay for a second opinion by a network provider. Only one of the respondents will routinely pay for a second opinion provided by a non-network provider. The other ten may pay for a second opinion at a NCI comprehensive cancer center under certain conditions, (ie. there is no in-network provider available; approval is received from the plan's medical director; or the enrollee receives a referral.) None of the respondents will provide coverage for second opinions at all of the NCI comprehensive cancer centers in the country but four of the eleven HMOs have at least one comprehensive cancer center in their network.

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 for second opinions from comprehensive cancer centers is available for individuals with indemnity policies; preferred provider organizations (for an additional payment); and HMO enrollees with point-of-service coverage. For HMO enrollees without point-of-service coverage, at least 4 of the 16 HMOs in Virginia have at least one comprehensive cancer center in their network.

The comments from the Cullather Center noted that NCI comprehensive centers offer more clinical trials and see greater volumes of patients. A CEO of a comprehensive cancer center commented that federally designated centers provide cutting edge treatments that are not usually available at community hospitals.[45]

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.

According to information received from a cancer center in Virginia, and from proponents of House Bill 2156, the state employee health plan, and HMOs responding to a Bureau of Insurance survey, costs for second opinion visits range from $90 to $600, with one source indicating a cost of up to $2,000. Multiple visits may be needed for the evaluation.

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

Two concerned citizens spoke at the public hearing in support of House Bill 2156. One speaker described in detail the amount of time and energy that she utilized trying to receive approval to obtain a second opinion for her husband at a comprehensive cancer center. The center was recommended to the patient by his treating physician. Information from the Duke Comprehensive Cancer Center indicated that in 2005, 482 patients with primary brain tumors (including 39 Virginians), were seen at the facility for the first time.[46]

The JLARC assessment estimates that approximately 60 new primary brain tumor patients annually will be affected by House Bill 2156 based on the incidence rate for primary brain tumors and current insurance coverage.[47]

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

One letter of support was received from a comprehensive cancer center, and one letter of support was received from the Cullather Center. Another letter of support for the bill was received from a member of the General Assembly. The level of support from other providers is not known. Two citizens spoke in support of the bill at the public hearing.[48]

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 the interest of collective bargaining organizations on 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 mandated benefit.

Information was received from the Virginia Cancer Registry regarding the number of primary malignant brain tumors reported in the past five years.

**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.

House Bill 2156 is not expected to impact the cost of second opinion evaluations for brain tumors over the next five years. Based on information from the Virginia Cancer Registry, less than 500 Virginians have been diagnosed with primary brain tumors each year in the past five years. Some of the 500 would seek and receive a second opinion in a setting other than a comprehensive cancer center.[49]

The JLARC assessment estimates that in 2006, 560 patients in Virginia were newly diagnosed with a primary malignant brain tumor based on data collected by the CBTRUS.[50]

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

The inappropriate use of second opinions is not expected to increase as a result of the proposed legislation. A second opinion evaluation is considered an accepted medical procedure. Appropriate use of second opinions at NCI comprehensive cancer centers could increase but the numbers would be low because approximately 500 Virginians develop primary malignant brain tumors each year.

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

Most insured Virginians already have coverage for second opinion evaluations at comprehensive cancer centers. For those without coverage, the bill might provide coverage for a more expensive second opinion. Proponents of House Bill 2156 estimated a cost of approximately $600 for second opinions from comprehensive cancer centers. Estimates from other sources for second opinions at other facilities ranged from $90 to $300. The Cullather Center noted that the financial impact or burden on insurers would be minimal.[51]

The JLARC assessment reported a range of $300 to $900 for second opinions from comprehensive cancer centers for a single consultation and charges of approximately $300 from two university health systems in Virginia.[52]

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 comprehensive cancer centers. The number of Virginians with primary brain tumors is small and not all of the individuals with brain tumors will seek a second opinion from a comprehensive cancer center if coverage is mandated.

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 2007 survey by the Bureau of Insurance provided some information on the estimated premium impact of the proposed mandate. Five companies provided cost estimates ranging from $.10 to $1.00 per month to provide the coverage required by House Bill 2156 in individual contracts. Four companies estimated costs ranging from $.21 to $3.00 for providing the coverage on an optional basis for individual contracts. Ten companies estimated costs ranging from $.00 to $2.60 for standard group coverage. Three companies estimated a cost of $.20 per month to offer the coverage for group contracts and one company estimated a cost of $1.37 per month.

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

House Bill 2156 is not expected to have a significant impact on the total cost of health care. The number of people with malignant brain tumors is low. Many of the individuals that will develop the tumors will already have access to second opinion evaluations at NCI comprehensive cancer centers because of coverage through indemnity contracts, or PPOs or HMOs with a point-of-service feature.

**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.

The value of second opinion evaluations for cancer patients is widely accepted. The American Cancer Society, American Brain Tumor Association, and the CBTRUS all note the value of second opinions for brain cancer patients. [53]

A study by the Department of Pathology at Johns Hopkins Medical Institutions, "Mandatory Second Opinion Surgical Pathology at a Large Referral Hospital" found that a review of 6,171 cases indicated a second opinion resulted in a change of diagnosis in 1.4% of the cases.[54]

Specific studies on the benefit of receiving a second opinion evaluation for primary malignant brain tumors from NCI comprehensive cancer centers were not found.

Proponents of House Bill 2156 point to studies by Enzinger, Holt, and Meyerhardt that document the affect of the volume of patients treated at a particular institution makes a difference in the "quality of outcomes for patients." The Cullather Center notes that some comprehensive cancer centers treat as many as 1,000 new brain tumor patients annually and that Duke is monitoring 3,000 patients with brain tumors. The Cullather Center stated that less than 100 brain tumors patients each year are treated at cancer centers like UVA and VCU.[55]

A comprehensive cancer center officer noted that such centers develop therapies and treatment protocols that provide information for all practicing physicians. He noted the expertise available at his facility's Brain Tumor Program that makes the latest and most advance treatment modalities available to patients.[56]

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 proposal is consistent with the role of health insurance. Proponents believe the bill addresses the need for people with a catastrophic disease to explore options to extend their lives without the burden of paperwork and numerous contacts with their insurer or HMO. The proposal addresses a serious medical condition.

However, those who oppose the bill believe that current coverage for second opinions is sufficient. VAHP believes that House Bill 2156 would not improve access to care or the quality of care for Virginians with primary malignant brain tumors.[57]

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

The proposed mandate is expected to add only minimal cost to the health care coverage for all policyholders. The number of individuals in Virginia developing malignant brain tumors each year is relatively low (approximately 500 people.) Many of those individuals would not seek an opinion from a NCI comprehensive cancer center, and others already have access to the comprehensive centers.

The JLARC assessment notes that it is not clear if the mandate would address patient needs. The assessment noted that not all comprehensive cancer centers have brain tumor centers, and that the majority of clinical trials for brain tumors on NCI's database are not conducted at comprehensive cancer centers. Access to clinical trials and investigational and new treatments and approaches were mentioned often as one of the reasons patients sought care at comprehensive centers. The JLARC findings suggest that a revision of the current mandate of coverage for clinical trials required by Section 38.2-3418.8 could possibly address the concerns of proponents that initial clinical trial evaluations are difficult for patients to obtain.[58]

c. The extent to which the need for the 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. It is unlikely that many individuals would

anticipate developing a brain tumor and purchase coverage for treatment or an evaluation at a NCI comprehensive cancer center it a diagnosis was not anticipated.

The JLARC assessment noted that purchasers of health insurance would probably not consider the purchase of this coverage to be critical.[59]

## Recommendation

The Advisory Commission voted on September 20, 2007 to recommend against the enactment of House Bill 2156 (Yes-5, No-4).

## Conclusion

The Advisory Commission members recognized the expertise available at NCI comprehensive cancer centers. However, the Advisory Commission had concerns about the need to require the proposed coverage from one type of facility when coverage for second opinions for primary brain tumors is currently available at many facilities in the state for most Virginians with health care coverage. Two NCI cancer centers that treat brain cancer patients are located in Virginia, and many Virginians with coverage have access to NCI comprehensive cancer centers in other states.

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