JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY

EVALUATION OF PROPOSED MANDATED HEALTH INSURANCE BENEFITS

Evaluation of House Bill 2156: Mandated Coverage of Second Opinions for Primary Malignant Brain Tumor Patients at NCI Comprehensive Cancer Centers

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Laura Lee O. Viergever

JLARC Staff for This Evaluation

Hal Greer, Division Chief
Kimberly A. Sarte, Principal Fiscal Analyst

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This evaluation is available on the JLARC website at http://jlarc.state.va.us

Evaluation of House Bill 2156: Mandated Coverage of Second Opinions for Primary Malignant Brain Tumor Patients at NCI Comprehensive Cancer Centers

JLARC SUMMARY

House Bill 2156 would mandate health insurance coverage of second opinion evaluations for primary malignant brain tumor patients at any of the 39 Comprehensive Cancer Centers designated by the National Cancer Institute (NCI) across the United States. There are no NCI Comprehensive Cancer Centers in Virginia, but there are two NCI-designated Cancer Centers in the State.

MEDICAL EFFICACY AND EFFECTIVENESS

Medical experts at two Virginia medical schools, NCI, and several Comprehensive Cancer Centers in the mid-Atlantic region indicated that while it is preferable for patients to receive a second opinion evaluation at a multidisciplinary cancer center, it is not necessary that it be a Comprehensive Cancer Center. Staff at NCI and several Comprehensive Cancer Centers further indicated that the university health systems in Virginia (also the NCI Cancer Centers in the State) would be equally competent at providing a second opinion as a Comprehensive Cancer Center. Helping primary malignant brain tumor patients gain access to clinical trials is another rationale for the proposed mandate. However, data from NCI shows that the majority of clinical trials are not held at Comprehensive Cancer Centers.

In This Evaluation

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SOCIAL IMPACT

Patients most impacted by the proposed mandate would be those enrolled in fully insured health maintenance organizations (HMOs)–an estimated 60 new primary malignant brain tumor patients annually. None of the HMOs responding to a Bureau of Insurance (BOI) survey provide the proposed coverage at all Comprehensive Cancer Centers. However, about one-third indicated that some of these centers are included in their networks. The remaining two-thirds indicated that even though these centers are not in their networks, they may provide coverage for a second opinion at these centers in certain situations. Further, many HMOs offer optional features that provide patients with out-of-network coverage. In addition to HMOs, patients covered through individual plans (less than five percent of Virginians) could also be affected by the proposed mandate. It appears that even among patients that have the proposed coverage, relatively few (one to six percent) obtain second opinion evaluations at Comprehensive Cancer Centers. For those patients without coverage, some may be able to pay for the benefit out-of-pocket; others may be able to access similar evaluations through Virginia's clinical trials mandate.

FINANCIAL IMPACT

The proposed mandate is not expected to have a measurable impact on the cost of second opinions or providers of second opinions due to the small number of patients involved. Any increase in premiums is also expected to be minor (median estimates are about $0.20 monthly), probably less than that of any existing mandates. The impact on the total cost of health care is expected to be negligible due to the small number of patients affected and the narrow scope of the proposed mandate.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

The proposed mandate is consistent with the role of health insurance and is not expected to have a significant impact on cost. However, it does not appear to be the best way to address the concerns of advocates and patients. Medical experts at Comprehensive Cancer Centers in the mid-Atlantic region, NCI, and two Virginia medical schools indicate that it is not necessary to gain access to a Comprehensive Cancer Center to obtain a high-quality, multidisciplinary second opinion. If a concern among advocates is ensuring that patients have access to clinical trials and are aware of other investigational treatments, then it appears that strengthening the clinical trials mandate to ensure that insurance companies cover the initial clinical trial evaluation would more directly address patient needs than the provisions of the proposed mandate.

Evaluation of House Bill 2156: Mandated Coverage of Second Opinions for Primary Malignant Brain Tumor Patients at NCI Comprehensive Cancer Centers

House Bill 2156 of the 2007 General Assembly Session would mandate health insurance coverage for a second opinion evaluation for primary malignant brain tumor patients at medical centers designated by the National Cancer Institute (NCI) as Comprehensive Cancer Centers. There are no NCI Comprehensive Cancer Centers in Virginia.

BACKGROUND

A primary malignant brain tumor is a complex condition, and the prognosis for many patients diagnosed with these tumors remains poor. Second opinion evaluations are often recommended for these patients to confirm their diagnosis and to compare treatment options. HB 2156 would require insurers to cover second opinion evaluations for these patients at any of the 39 NCI Comprehensive Cancer Centers across the United States. (See Appendix E for locations of these centers.)

a. Description of Medical Condition and Proposed Treatment

The following section provides background information on brain tumors, the provision of a second opinion, and the requirements of NCI Comprehensive Cancer Centers.

Brain Tumors. A brain tumor is a mass of cells in the brain that has grown and multiplied uncontrollably. Primary brain tumors originate in the brain whereas metastatic brain tumors come from cancer cells in another part of the body. Primary brain tumors can be either benign or malignant. Malignant brain tumors contain cancer cells and are more serious and life-threatening than benign tumors.

Although there are many different types, primary malignant brain tumors can generally be classified into two groups: gliomas and non-glial tumors. Gliomas are the most common type and arise from glial cells that surround and support the neurons (nerve cells) in the brain. Non-glial tumors develop on or in other structures within the brain, such as nerves, blood vessels, and glands. Tu-

mors are also categorized according to their aggressiveness on a scale of 1 (least aggressive) to 4 (most aggressive). Many tumors are categorized as aggressive at the time of discovery.

The exact causes of brain tumors are unknown. However, primary brain tumors generally are more common in males than females, occur more often among white people than in other races, increase in incidence as people get older, and seem to occur more frequently in some families. Brain tumors are more common in adults than in children in terms of the number of people affected. However, they are the second most common malignancy among children, involving 20 percent of pediatric cancer cases.

The symptoms of brain tumors vary according to the function of the brain tissue they are invading or compressing. In addition to headaches, nausea, and seizures, symptoms can include changes in speech, vision, or hearing; problems balancing or walking; problems with memory; and changes in mood, personality, or ability to concentrate and other cognitive problems. For these reasons, brain tumors are different from other types of cancer and are often perceived as an attack on the whole person and on his or her identity. The average age of diagnosis for an adult is 54, so these patients are often the key supporters of their families. However, patients may suddenly be unable to manage family decisions, maintain prior income, or operate a motor vehicle.

Although there have been advances in treatment for primary malignant brain tumors, the prognosis for many of these patients remains poor. The median survival time for patients diagnosed with the most common type of primary brain tumor is only about a year from the time of diagnosis, even with aggressive treatment.

Second Opinion Evaluations. After receiving the diagnosis of a primary malignant brain tumor, some patients seek a second opinion and brain tumor organizations such as the National Brain Tumor Foundation recommend that they do so. Some insurance companies also require that a patient get a second opinion before undergoing major therapy. Second opinions can confirm the initial diagnosis and allow the patient to compare the suggested courses of treatment. These evaluations are particularly important for primary malignant brain tumor patients due to the complex nature of their tumors. Further, several studies have found that the discrepancy rates in diagnosis of these tumors are fairly high, ranging from 23 percent to 43 percent. These studies also found that for those tumors with a discordant diagnosis, 16 to 28 percent were considered significant enough to affect patient management and/or prognosis.

A second opinion is a review of the cancer diagnosis and the treatment recommendations of the treating physician by another, independent physician or team of physicians. Either the patient or the primary physician can initiate a second opinion. The second opinion consultant(s) will typically review copies of x-ray films, hospital records, pathology slides and records, and operative reports of any surgeries related to the cancer. The consultant(s) will go over all findings with the patient and will prepare a written report that will be submitted to the treating physician and patient. Second opinions are more likely to be comprehensive when performed in a cancer center with a multidisciplinary team, which usually includes surgeons, oncologists, radiation therapists, and subspecialist oncologists.

NCI Comprehensive Cancer Centers. House Bill 2156 would mandate health insurance coverage of second opinion evaluations for primary malignant brain tumor patients at any NCI Comprehensive Cancer Center. A Comprehensive Cancer Center is one of two types of NCI-designated cancer centers; the other type is a Cancer Center. NCI staff indicate that the primary difference is that Comprehensive Cancer Centers must have a credible research program in population sciences, such as preventive sciences or epidemiological studies. While many Cancer Centers conduct research in these areas, their research program may not rise to the level of a Comprehensive Cancer Center. NCI explicitly states that "the terms NCI-designated Comprehensive Cancer Center and NCI-designated Cancer Center do not denote a difference in the quality of care they provide to patients."

NCI-designated Cancer Centers

Comprehensive Cancer Centers: Conduct research and provide services directly to cancer patients. Must do the following: (1) demonstrate expertise in laboratory, clinical, and behavioral and population-based research, (2) initiate and conduct early phase, innovative clinical trials, (3) participate in NCI cooperative groups by providing leadership and recruiting patients for trials, and (4) conduct outreach and educational activities and provide information on advances in healthcare to healthcare professionals and the public.

Cancer Centers: Conduct a combination of basic, population sciences, and clinical research. Encouraged to stimulate collaborative research. Not all provide patient care, but those that do are expected to conduct early phase, innovative clinical trials and participate in NCI cooperative groups.

In 2007, there were 39 Comprehensive Cancer Centers in the United States. (See Appendix E for locations of these centers.) Virginia has no Comprehensive Cancer Centers but has two Cancer Centers – the University of Virginia (UVA) Medical Center and the Massey Cancer Center at Virginia Commonwealth University (VCU).

b. History of Proposed Mandate

During the 2006 General Assembly Session, a related brain tumor mandate (HB 623) was introduced. House Bill 623 would have required insurers to cover treatment for malignant brain tumors at NCI-designated cancer centers within 300 miles of the patient's residence. Subsequent to the October 17, 2006, public hearing of the Special Advisory Commission on the bill, the patron requested that the bill be changed to require coverage of second opinions at NCI Comprehensive Cancer Centers and Phase III clinical trials for primary malignant brain tumors, but not treatment. At a November 20, 2006, meeting, the Special Advisory Commission voted against recommending the original bill (HB 623). The patron sub-

sequently withdrew the proposed revisions to HB 623 from consideration by the Commission. In 2007, HB 2156 was introduced which incorporated the second opinion coverage in the proposed revision to HB 623.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of HB 2156 will have the opportunity to officially express their views at the public hearing on July 18, 2007, conducted by the Special Advisory Commission on Mandated Health Insurance Benefits. Proponents of the bill appear to be advocates for patients with primary malignant brain tumors, including representatives of the Cullather Brain Tumor Quality of Life Center at St. Mary's Hospital in Richmond. Advocates indicate that patients should have the ability to learn about their treatment options, including potential clinical trials or investigational treatments, such as off-label uses of pharmaceuticals, regardless of whether they have insurance coverage for all available options.

The main opposition to the proposed mandate appears to be from the health insurance industry. Industry representatives oppose the bill because they indicate that mechanisms are already in place to allow patients access to Comprehensive Cancer Centers if they are not in their health plan's network. In addition, patients have access to Phase II through Phase IV clinical trials at such facilities due to an existing cancer clinical trials mandate in Virginia. Because investigational treatments (which are not conducted through clinical trials) are rarely, if ever, covered by insurance, industry representatives feel that allowing patients to gain knowledge of investigational treatments utilized at out-of-network facilities would give them false hope regarding unproven therapies for which they would not have insurance coverage.

Clinical Trials

Clinical trials are categorized as Phase I through Phase IV, depending on how far the research has progressed. Phase I is the earliest phase of clinical trial with Phase IV being the final phase. Many treatments being researched never make it to a Phase IV trial.

MEDICAL EFFICACY AND EFFECTIVENESS

JLARC staff reviewed the literature and did not find any medical research evaluating the effectiveness of receiving a second opinion for primary malignant brain tumor patients at NCI Comprehensive Cancer Centers (see bibliography in Appendix D). JLARC staff also contacted medical experts at two Virginia medical schools, NCI, and several Comprehensive Cancer Centers in the mid-Atlantic region. These experts indicated that while it is preferable for patients to receive a second opinion evaluation at a multidisciplinary cancer center, it is not necessary that it be a Comprehensive Cancer Center. Staff at NCI and several Comprehensive Cancer Centers further indicated that the university health systems in Virginia would be equally competent at providing a second opinion as a Comprehensive Cancer Center. Helping primary malignant

brain tumor patients gain access to clinical trials is another rationale for the proposed mandate. However, data from NCI shows that the majority of clinical trials are not conducted by Comprehensive Cancer Centers. (Coverage for clinical trials or investigational treatments, such as off-label uses of pharmaceuticals, would not change as a result of HB 2156.)

a. Medical Efficacy of Benefit

Medical Efficacy

Assessments of medical efficacy are typically based on clinical research, particularly randomized clinical trials, demonstrating the success of a particular treatment compared to alternative treatments or no treatment at all.

Medical efficacy refers to the success of a particular treatment based on its evaluation under controlled conditions, rather than a normal clinical setting. While research supports the importance of second opinions generally (see bibliography in Appendix D), JLARC staff found no studies specifically evaluating the efficacy or effectiveness of primary malignant brain tumor patients receiving a second opinion at NCI Comprehensive Cancer Centers.

b. Medical Effectiveness of Benefit

Medical Effectiveness

Medical effectiveness refers to the success of a particular treatment in a normal clinical setting as opposed to ideal or laboratory conditions.

As mentioned previously, due to the complex nature of brain tumors, it is often advisable for patients with primary malignant brain tumors to obtain a second opinion. A second opinion can confirm the patient's diagnosis and compare suggested courses of treatment. Most patients covered through fully insured health plans already have the ability to obtain a second opinion, although they may not have the option to do so at a Comprehensive Cancer Center. While there seems to be agreement that it is beneficial for primary malignant brain tumor patients to receive a second opinion from a multidisciplinary cancer center with a brain tumor center, there is not a consensus that it is necessary or preferred for patients to receive a second opinion specifically from a Comprehensive Cancer Center.

Medical Experts in Virginia. Medical experts consulted at two Virginia medical schools indicated that it is important for primary malignant brain tumor patients to have access to a second opinion at a brain tumor center with a skilled medical team and available innovative clinical trials. However, while these services may be available at some, they are not available at all Comprehensive Cancer Centers. In addition, these services may be available at cancer centers that are not designated Comprehensive Cancer Centers. For example, neither the University of Virginia (UVA) nor Virginia Commonwealth University (VCU) are designated Comprehensive Cancer Centers. However, both medical centers have established brain tumor centers led by fellowship-trained brain tumor specialists and conduct clinical trials for brain tumors. In contrast, the Cancer Institute of New Jersey at Robert Wood Johnson University Hospital, which is a designated Comprehensive

Cancer Center, currently does not have a brain tumor center, provides few second opinions for brain tumors, and conducts few, if any, clinical trials for brain tumors.

Medical Experts at NCI and Regional Comprehensive Cancer Centers. JLARC staff contacted the national NCI office and 13 Comprehensive Cancer Centers in the mid-Atlantic region to obtain information on several issues, including the advantages of receiving a second opinion at a Comprehensive Cancer Center versus other cancer centers, such as an NCI Cancer Center. Staff at NCI did not report a benefit to seeking a second opinion from a Comprehensive Cancer Center compared to a Cancer Center, and they emphasized that Cancer Centers and Comprehensive Cancer Centers are equally good at the clinical aspects of patient care. NCI staff also indicated that there are many clinical trials conducted at centers outside of Comprehensive Cancer Centers, so this would not be a valid reason to require coverage of a second opinion at Comprehensive Cancer Centers. Further, NCI staff stated that the two Cancer Centers in Virginia would be as qualified in providing a second opinion as Comprehensive Cancer Centers for issues such as misdiagnosis of tumors.

Of the seven Comprehensive Cancer Centers responding to JLARC's requests, most mentioned the specialized expertise and multidisciplinary teams available at Comprehensive Cancer Centers as a potential advantage of these centers. However, four indicated that they did not believe it was necessary for primary malignant brain tumor patients to receive their second opinion specifically at a Comprehensive Cancer Center. (The remaining three did not address this specific issue.) These Centers emphasized that multidisciplinary brain tumor teams at university hospitals could be as good at providing second opinions as at a Comprehensive Cancer Center, and they specifically referenced the programs available at UVA and VCU.

Location of Clinical Trials. One of the reasons given by advocates for the proposed mandate is to help primary malignant brain tumor patients gain access to clinical trials. (Insurance coverage for clinical trials or investigational treatments, such as off-label uses of drugs, would not change as a result of HB 2165.) Clinical trials are particularly important for these patients because, unlike many other forms of cancer, there currently are no conventional treatments that have led to significant increases in life expectancy for primary malignant brain tumors. In fact, NCI lists clinical trials as one of the top treatment options for nearly every type of adult primary malignant brain tumor. This is not true for many other types of cancer where specific surgery, radiation, or chemotherapy treatments are identified. However, while it is the case that certain Comprehensive Cancer Centers, including at Duke Univer-

sity, Herbert Irving Comprehensive Cancer Center at Columbia University, and Memorial Sloan-Kettering Cancer Center, conduct a large number of clinical trials for primary malignant brain tumors, this is not true of all Comprehensive Cancer Centers. In fact, the majority of clinical trials for primary malignant brain tumors are not conducted at Comprehensive Cancer Centers.

NCI's Physician Data Query (PDQ) database tracks clinical trials across the United States and abroad by a variety of characteristics, including trial site and trial phase. JLARC staff conducted an assessment of the open clinical trials for primary malignant brain tumors in March of 2007 in the mid-Atlantic region, defined as Maryland, New Jersey, New York, North Carolina, Pennsylvania, Tennessee, Virginia, and West Virginia. An assessment of all Phase I through Phase III clinical trials (there were no open Phase IV clinical trials during this time period) for primary malignant brain tumor patients revealed that more than 70 percent of open clinical trials were not being held at Comprehensive Cancer Centers during this period. For children, an even greater share of trials, approximately 80 percent, were not held at Comprehensive Cancer Centers, in part due to the large number of trials held at children's hospitals.

Brain tumor patients seeking new, innovative treatments are most likely to be interested in access to Phase III clinical trials because these trials are more likely to demonstrate whether the treatment is superior to standard forms of treatment. (Phase I and Phase II trials are concerned primarily with determining the safe dosage levels of a new treatment and whether the treatment has an effect on the cancers being studied.) For Phase III trials, an even greater percentage (nearly 80 percent) of all trials for primary malignant brain tumor patients were not held at Comprehensive Cancer Centers. (For children, the proportion of Phase III clinical trials not held at Comprehensive Cancer Centers remained about the same.) This is likely because Phase III trials often need to be held at more than one medical center due to the number of participants required for a Phase III trial. Also, some brain tumor centers at Comprehensive Cancer Centers do not routinely participate in Phase III clinical trials.

SOCIAL IMPACT

Individuals most impacted by the proposed mandate would be those in enrolled health maintenance organizations (HMOs). None of the HMOs responding to a Bureau of Insurance (BOI) survey provide the proposed coverage at all Comprehensive Cancer Centers. However, about one-third of HMOs indicated that they include some of these centers in their networks. The remaining two-thirds indicated that even though they do not include Comprehen-

sive Cancer Centers in their networks, they may provide coverage for a second opinion at these centers in certain situations. Further, many HMOs offer a Point of Service (POS) feature that provides patients coverage if they go out of network. In addition to HMOs, patients covered through individual plans with significant plan limitations could also be affected by the proposed mandate. It appears that even among patients that have the proposed coverage, relatively few obtain second opinion evaluations at Comprehensive Cancer Centers. For those patients without coverage, some families may be able to pay for the benefit out-of-pocket. Patients may also be able to gain access to similar types of evaluations through Virginia's clinical trials mandate.

a. Utilization of Treatment

Data are not available statewide on the proportion of primary malignant brain tumor patients who obtain a second opinion at a Comprehensive Cancer Center. However, data provided by the State employee health plan, UVA, VCU, and several Comprehensive Cancer Centers in the mid-Atlantic region indicate that number is likely quite low.

Four to eight percent of primary malignant brain tumor patients covered by the State employee health plan are estimated to have received a second opinion in the past three years, but only one to two percent are estimated to have received a second opinion at a Comprehensive Cancer Center. (Enrollees in the State health plan have access to Comprehensive Cancer Centers through Anthem's Blue Card program.) It is difficult to determine how many patients receive second opinion consultations because there is not a specific medical billing code for this purpose. However, an analysis that isolated incidences where patients received a consultation(s) at a facility that was different from their treating facility revealed that an estimated one to two percent of patients received such consultations at a Comprehensive Cancer Center

VCU and UVA also reported similarly low percentages of patients receiving second opinions at Comprehensive Cancer Centers. VCU estimates that approximately five to six percent of their primary malignant brain tumor patients receive a second opinion at a Comprehensive Cancer Center, and UVA estimates that approximately one to two percent of their patients receive a second opinion at a Comprehensive Cancer Center. This is not to say that VCU and UVA patients do not get second opinions; just that they do not rely on Comprehensive Cancer Centers for these opinions.

Several Comprehensive Cancer Centers in the mid-Atlantic region (the Cancer Institute of New Jersey at the Robert Wood Johnson Medical School, Roswell Park Cancer Institute, Memorial Sloan-

Kettering, the UNC Lineberger and Wake Forest Comprehensive Cancer Centers, and Fox Chase Cancer Center) also indicated that they provide very few second opinions to primary malignant brain tumor patients from Virginia. The Comprehensive Cancer Centers at Johns Hopkins (Baltimore) and Duke University (Durham, North Carolina), two of the facilities where Virginia patients are more likely to go, did not provide information on the number of Virginia patients seeking second opinions. Staff at Johns Hopkins indicated that they do not track this information and that their brain tumor specialists are in such great demand, they "do not encourage patients to seek only second opinions per se, as they take a slot away from patients who may want to enter [their] system for treatment." Johns Hopkins also indicated that, when they do provide second opinions, a percentage of those patients decide to remain there for treatment.

b. Availability of Coverage

Virginia patients most affected by the proposed mandate would likely be those enrolled in health maintenance organizations (HMOs) because their network of providers may be more restricted compared to other health plan types. Current data is not available on the proportion of individuals in fully insured plans that are members of HMOs. However, the U.S. Census Bureau indicates that 22 percent of all Virginians were enrolled in an HMO in 2004. Based on a 2003 national estimate that approximately 50 percent of privately insured individuals are in self-funded plans, a reasonable estimate is that approximately 11 percent of all Virginians are covered through fully insured HMOs. Patients enrolled in preferred provider organization plans (PPOs) already have access to Comprehensive Cancer Centers through either their in-network or out-of-network coverage. If a Comprehensive Cancer Center is out-of-network, these patients could pay greater out-of-pocket expenses, and the proposed mandate will not alter this financial arrangement. Patients covered through individual plans (approximately five percent of Virginians) could be affected by the proposed mandate due to the additional limitations often placed on such plans, even when out-of-network coverage is available.

None of the HMOs responding to a 2007 Bureau of Insurance (BOI) survey of health insurance providers include coverage for second opinions for primary malignant brain tumors at all Comprehensive Cancer Centers as part of their standard benefit. However, about one-third of HMOs (four of eleven responding to the survey) indicated that while they do not provide coverage at all Comprehensive Cancer Centers, they include some of these centers in their networks. Most of these HMOs include several of the Comprehensive Cancer Centers in the mid-Atlantic region. The remaining seven HMOs indicated that even though they do not in-

clude any Comprehensive Cancer Centers in their networks, they may provide coverage for a second opinion at these centers in certain situations, such as with an approved referral. Further, many HMOs have an optional POS feature that provide patients coverage if they go out of network. Therefore, while the 11 percent of Virginians enrolled in fully insured HMOs do not appear to have coverage at all Comprehensive Cancer Centers, about one-third of these individuals have coverage at some Comprehensive Cancer Centers. The remaining two-thirds of Virginians in fully insured HMOs may be able to obtain coverage in certain situations, and many of these patients may have optional POS features that would provide coverage out-of-network. Based on the BOI survey results, all Virginian's enrolled in HMOs would to have coverage to receive a second opinion at a cancer center in Virginia.

Fifteen of 17 insurance companies offering non-HMO plans (PPO and indemnity plans) responding to the BOI survey indicated that the proposed benefit is part of their standard benefit package. For the remaining two non-HMO plans, enrollees would presumably have this benefit through their out-of-network coverage. (Survey results in this section may differ slightly from those reported in the draft BOI report due to several late survey responses.)

Patients covered through individual plans may have coverage at Comprehensive Cancer Centers depending on their plan. However, even if patients have out-of-network coverage with these plans, they may be limited by other plan restrictions, such as limits on numbers of visits or payment maximums.

A technical issue with the proposed mandate is that language is included indicating that the mandate 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 persons with Medicare or any similar state or federal government plan. This language is included in most mandates. However, since the proposed mandate addresses malignant brain tumors, it may not be the intention to exclude cancer policies from the mandate. Therefore, BOI has suggested a technical amendment indicating that the mandate does not apply to limited or specified disease policies other than cancer policies.

c. Availability of Treatment/ Benefit

House Bill 2156 would allow primary malignant brain tumor patients to obtain a second opinion evaluation at any NCI Comprehensive Cancer Center. As of February 2007, there were 39 Comprehensive Cancer Centers across the United States (see Appendix E.) Among the Mid-Atlantic states where Virginia patients would

be most likely to obtain a second opinion, there are 13 Comprehensive Cancer Centers:

New York

- Roswell Park Cancer Institute
- Memorial Sloan-Kettering Cancer Center
- Herbert Irving Comprehensive Cancer Center at Columbia University

New Jersey

- The Cancer Institute of New Jersey at Robert Wood Johnson Medical School

Pennsylvania

- Abramson Cancer Center of the University of Pennsylvania
- Fox Chase Cancer Center
- University of Pittsburgh Cancer Institute

Maryland

- The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

District of Columbia

- Lombardi Comprehensive Cancer Center at Georgetown University Medical Center

North Carolina

- UNC Lineberger Comprehensive Cancer Center at the University of North Carolina at Chapel Hill
- Duke Comprehensive Cancer Center
- Wake Forest Comprehensive Cancer Center at Wake Forest University

Tennessee

- Vanderbilt-Ingram Cancer Center at Vanderbilt University

d. Availability of Treatment Without Coverage

As will be discussed in the next section, the cost of a second opinion evaluation for a primary malignant brain tumor at a Comprehensive Cancer Center is relatively modest in comparison to median household income. Therefore, in at least some cases, it appears that patients would have the ability to seek a second opinion at one of these centers even without insurance coverage. However, as indicated in the background of this evaluation, some families may experience significant financial difficulty after the diagnosis of a primary malignant brain tumor, particularly if the

patient is one of the primary income earners for the household. In these cases, even the relatively modest cost of obtaining a second opinion at a Comprehensive Cancer Center may be out of reach. However, these patients would still likely have the option of obtaining a second opinion at a cancer center in Virginia where they would have coverage.

If patients do not have coverage for a second opinion at a Comprehensive Cancer Center, they may be able to obtain coverage for this type of evaluation through Virginia's cancer clinical trial mandate. This option may be particularly relevant because advocates for HB 2156 indicate that one of the main reasons for the proposed mandate is for patients to be aware of clinical trials being held at Comprehensive Cancer Centers.

Virginia's cancer clinical trials mandate requires insurers to provide coverage for patient treatment costs during Phase II through Phase IV clinical trials. Treatment costs provided in a Phase I trial may be covered on a case-by-case basis. Both BOI and the Virginia Association of Health Plans (VAHP) confirmed that, as a result of this mandate, if there are no comparable trials conducted within a health plan's network (which often is primarily within Virginia), the health plan must provide coverage for a clinical trial outside of the network, including at an out-of-state Comprehensive Cancer Center. VAHP also indicated that insurers interpret the mandate to include the initial evaluation required to determine eligibility for a clinical trial, although VAHP indicated that patients should consult with their plan prior to obtaining the evaluation. (Medical experts indicate that the type of evaluation required to determine eligibility for a clinical trial is very similar to a second opinion evaluation.) However, advocates for the proposed mandate cite cases of patients being unable to obtain an evaluation at a Comprehensive Cancer Center to determine eligibility for a clinical trial due to lack of insurance coverage.

e. Financial Hardship

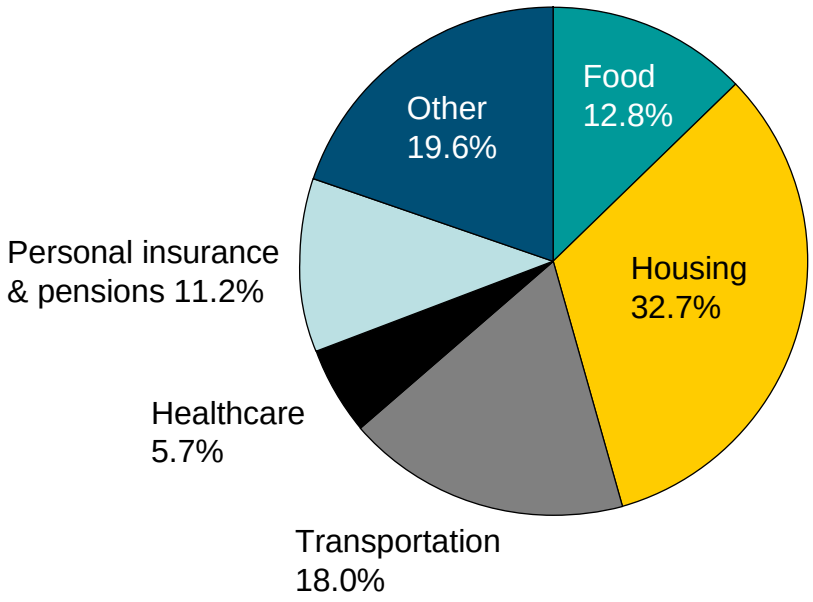
The financial hardship for primary malignant brain tumor patients seeking a second opinion at a Comprehensive Cancer Center would be greatest for patients enrolled in an HMO plan that does not include any such centers in its network and possibly patients in individual plans with very restricted benefits. These patients could potentially be responsible for the full amount of charges for the second opinion. Information provided by two Comprehensive Cancer Centers in the mid-Atlantic region and by advocates for the proposed mandate indicated that the full charge for providing a second opinion evaluation for a primary malignant brain tumor at a Comprehensive Cancer Center ranges from $300 to $600. However, a third Comprehensive Cancer Center indicated the charge

for a single second opinion consult was more than $900. Staff at all three Comprehensive Cancer Centers indicated that a patient may require multiple consultations from different specialists as part of their second opinion, which could increase the overall cost. For example, if a patient saw specialists in each of medical (including chemotherapy), radiation, and surgical oncology, the combined cost of the second opinion could range from $900 to $2,700, depending on the length of time of each consultation. If additional blood tests or imaging studies were needed, the cost could be more.

Based on a median household income of $56,859 in Virginia in 2007, the cost of receiving a single second opinion consultation could range from 0.5 percent to 1.6 percent of median household income. The cost of receiving three second opinion consultations could range from 1.6 percent to 4.7 percent of median household income. As shown in Figure 1, these amounts are less than any of the major expenditure categories for typical U.S. households.

However, "median U.S. households" may not be representative of the situation of primary malignant brain tumor patients. As mentioned in the background section, brain tumors can be very debilitating and may have a significant impact on patients' income earn-

Figure 1: Distribution of Total Annual U.S. Household Expenditures by Major Category, 2005



Source: Bureau of Labor Statistics, Consumer Expenditure Survey, 2005

ing capacity. In such cases, the cost of a second opinion at a Comprehensive Cancer Center may be a greater financial hardship than for the median U.S. household. Also, travel costs may be a significant factor for patients depending on the location of the Comprehensive Cancer Center, and such costs are not covered by health insurance.

f. Prevalence/ Incidence of Condition

An estimated 560 patients were newly diagnosed with primary malignant brain tumors in Virginia in 2006. This estimate is based on data collected by the Central Brain Tumor Registry of the United States (CBTRUS). The incidence rate of primary malignant brain and central nervous system tumors nationally was 7.37 per 100,000 person years from 1998 to 2002. Virginia-specific incidence rates reported by CBTRUS are lower at 5.96 per 100,000. However, the Virginia rates are based on the Virginia Cancer Registry, and there is concern that the registry may be underreporting incidence rates. This appears to be confirmed by the fact that Virginia's incidence rate is measurably lower than the national rate and is the lowest of any state reporting incidence rates to CBTRUS.

g. Demand for Coverage

Interested parties will have the opportunity to formally voice their position on HB 2156 at the July public hearing before the Special Advisory Commission on Mandated Health Insurance Benefits. It is likely that demand for the coverage in the proposed mandate is relatively low. As indicated previously, individuals in HMOs who do not have coverage would be most affected by the proposed mandate. Based on the Virginia incidence rate reported above and the estimate that approximately 11 percent of Virginians are enrolled in fully insured HMOs that do not provide the proposed benefit as part of their standard coverage, there may be approximately 60 new primary malignant brain tumor patients annually that could be affected by the proposed mandate. However, as indicated previously, approximately one-third (about 20 patients) would already have coverage at some Comprehensive Cancer Centers, and the remaining two-thirds (about 40 patients) may have coverage from their HMO in certain situations, such as if they obtain an approved referral. Further, many HMO patients may have optional POS features in their plans which provide out-of-network coverage.

Patients in individual health plans with many coverage limitations may also be affected by the proposed mandate. Based on the previous estimate that approximately five percent of Virginians are en-

rolled in individual plans, at most an additional 30 new primary malignant brain tumor patients could be affected by the proposed mandate. However, some of these patients may be enrolled in HMOs and would be counted in the estimate above. Therefore, the number of additional patients in individual plans affected by the proposed mandate would be fewer than 30.

It is unlikely that all affected patients would request the coverage in the proposed mandate. As mentioned previously, it appears that even when individuals have coverage, few of them seek a second opinion at a Comprehensive Cancer Center. Only one to two percent of primary malignant brain tumor patients covered through the State employee health plan are estimated to have received second opinion evaluations at Comprehensive Cancer Centers. (These patients already have coverage at these centers through Anthem's Blue Card program.) VCU and UVA also report similarly low percentages of patients obtaining second opinions at Comprehensive Cancer Centers. Also, several Comprehensive Cancer Centers in the mid-Atlantic region indicated that they see few primary malignant brain tumor patients from Virginia for second opinion evaluations.

h. Labor Union Coverage

Labor unions do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages. Typically, labor unions advocate for broader benefits, rather than a benefit as specific as the proposed mandate. Therefore, it is more likely that they would advocate for "second opinions" in general rather than specifically by "Comprehensive Cancer Centers."

i. State Agency Findings

BOI and JLARC staff reviewed a related mandate proposal (HB 623) in 2006 that would have required coverage for treatment of malignant brain tumors at NCI-designated cancer centers within 300 miles of the patient's residence. The patron withdrew the proposed mandate from consideration by the Special Advisory Commission.

j. Public Payer Coverage

Both Medicare and Medicaid provide the level of coverage in the proposed mandate. There are no restrictions on where a Medicare patient receives services, as long as the provider is enrolled in Medicare. Similarly, Medicaid will cover services at facilities outside of Virginia, as long as the facility agrees to accept the reimbursement level for Virginia's Medicaid program.

k. Public Health Impact

The proposed mandate is not expected to impact public health because the potential benefits of the mandate would be directly received by patients and their families.

FINANCIAL IMPACT

The proposed mandate is not expected to have a measurable impact on the cost of second opinions or providers of second opinions due to the small number of patients involved and the relatively modest cost of conducting a second opinion. Any increase in premiums is also expected to be very minor, probably less than that of any existing mandates, if not negligible. The impact on the total cost of health care is expected to be negligible due to the small number of patients affected and the narrow scope of the proposed mandate, which only covers second opinions. The proposed mandate would not affect more costly aspects of patients' care, such as their ability to obtain treatment at a Comprehensive Cancer Center, gain access to clinical trials, or utilize investigational treatments.

a. Effect on Cost of Treatment

Due to the small number of patients involved, it is not expected that HB 2156 would have an impact on the cost of providing second opinion evaluations at Comprehensive Cancer Centers. This is particularly true if coverage in the mandate is limited to second opinions.

b. Change in Utilization

There will likely be only a small increase in the number of Virginia patients seeking second opinions at Comprehensive Cancer Centers due to the small number of individuals diagnosed with a primary malignant brain tumor annually. Further, many Virginia patients already have some level of coverage at Comprehensive Cancer Centers, yet only a small fraction seek a second opinion at these centers.

c. Serves as an Alternative

The proposed mandate would allow primary malignant brain tumor patients to receive second opinion evaluations at Comprehensive Cancer Centers. Most patients already have coverage to receive a second opinion evaluation, although it may not be at a Comprehensive Cancer Center.

The cost of a second opinion evaluation at a Comprehensive Cancer Center may be somewhat higher than at other cancer centers. Several Comprehensive Cancer Centers in the mid-Atlantic region indicated the charge for a single second opinion consultation ranges from $300 to $900, whereas two university health systems in Virginia reported a charge of about $300. The charge for a second opinion at a community hospital may be even less than at either a Comprehensive Cancer Center or a university hospital according to the 2006 JLARC review *Evaluation of HB 623: Mandated Coverage for Treatment of Malignant Brain Tumors at NCI Cancer Centers*. The review found that costs at high volume hospitals are approximately 10 percent higher than at lower volume hospitals. In addition, a patient would be more likely to receive multiple consultations as part of his second opinion evaluation at some Comprehensive Cancer Centers, although this would be the case with university hospitals as well.

d. Effect on Providers

Due to the relatively small number of patients affected by the mandate, the effect on Comprehensive Cancer Centers and other cancer centers is expected to be minimal, particularly if the mandate remains limited to second opinion evaluations. One Virginia university medical center indicated that most patients desiring a second opinion will figure out a way to obtain and pay for it anyway, regardless of insurance coverage, so centers may already be receiving most interested patients.

e. Administrative and Premium Costs

Administrative costs of the proposed mandate would likely be similar to other mandates. However, the impact on premiums would probably be less than most existing mandates if not almost nonexistent. (Survey results in this section may differ slightly from those reported in the draft BOI report due to several late responses.)

Administrative Expenses of Insurance Companies

The administrative expenses for insurance companies would likely be similar to other mandates. Insurance companies do not provide estimates on the administrative expenses separately in their responses to the BOI survey.

Premium and Administrative Expenses of Policyholders

Among over 25 insurance companies responding to a BOI survey on the proposed mandate, very few provided an estimate of monthly premium cost. (Nine additional companies responded that they did not conduct any business in Virginia that is impacted by mandates.) Five companies provided an estimate for individual

policyholders, and ten companies provided an estimate for group certificate holders (Table 1). Part of the low response rate for individual coverage appears to be that some insurance companies responding to the survey do not serve the individual market.

Among those companies providing individual coverage, monthly premium estimates range from $0.10 to $1.00 to provide the proposed coverage as part of the standard plan, and estimates range from $0.21 to $3.00 to provide the coverage as an option. The median premium estimate for both standard and optional coverage is $0.21 per month. This median premium estimate amounts to less than one one-hundredth of a percent of the average monthly premium for a standard single individual contract ($214), as defined in BOI's 2005 report on the financial impact of mandated health insurance benefits. As a result, the proposed mandate would probably have a smaller impact on premiums for individual coverage than any existing mandates. However, due to the very small sample size, it is difficult to know whether the premiums reported on the survey are representative of expected premium impacts.

Table 1: Estimated Monthly Premium Impact for HB 2156

	# of Responses	Lowest Estimate	Highest Estimate	Median Estimate
Individual (standard)	5	$0.10	$1.00	$0.21
Individual (optional)	4	$0.21	$3.00	$0.21
Group (standard)	10	$0.00	$2.60	$0.20
Group (optional)	4	$0.20	$1.37	$0.20

Source: Bureau of Insurance survey of insurance companies, 2007.

Among those companies providing group coverage, monthly estimates range from $0.00 to $2.60 to provide the proposed coverage as part of a standard plan, and estimates to provide coverage as an option range from $0.20 to $1.37. The median estimate for both standard and optional coverage is $0.20 per month. The BOI report on the financial impact of mandated health insurance benefits does not include information on the average monthly premium for group plans, so it is difficult to determine what proportion of the overall premium the proposed mandate would constitute. However, it is likely that the impact on monthly premiums would be relatively small compared to most existing mandates.

A public health expert consulted as part of this study indicated that the premium estimates provided by some insurance compa-

nies appear high, as it is unlikely that the modest costs of the additional consult could even be observed actuarially.

f. Total Cost of Health Care

The proposed mandate would have a negligible impact on the total cost of health care. The number of individuals affected by the mandate is very small, and many of these individuals may not choose to obtain a second opinion at a Comprehensive Cancer Center based on the behavior of patients who already have this option. For those that do, the cost of a second opinion is relatively modest compared with other medical expenses. The proposed mandate does not affect patients' existing coverage for more costly aspects of their care, such as obtaining treatment at a Comprehensive Cancer Center, gaining access to clinical trials, or utilizing investigational treatments, such as off-label uses of prescription drugs. (In addition to Virginia's clinical trials mandate, the *Code of Virginia* contains provisions requiring insurance coverage for off-label prescription drug use in some situations.)

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

The proposed mandate is consistent with the role of health insurance and is not expected to have a significant impact on cost. However, it does not appear that it would be the best way to address the concerns of advocates and patients. Medical experts at Comprehensive Cancer Centers in the mid-Atlantic region, NCI, and two Virginia medical schools indicate that it is not necessary to gain access to a Comprehensive Cancer Center to obtain a high quality, multidisciplinary second opinion. If a concern among advocates is ensuring that patients have access to clinical trials and are aware of other investigational treatments, then it appears that strengthening the clinical trials mandate to ensure that insurance companies cover the initial clinical trial evaluation would more directly address patient needs than the provisions of the proposed mandate.

a. Social Need/ Consistent With Role of Insurance

Based on the premise that the role of health insurance is to promote public health, encourage the use of preventative care, and to provide protection from catastrophic financial expenses for unexpected illnesses, the proposed mandate appears consistent with the role of health insurance. Most insurance companies already provide coverage for second opinion evaluations, and some even require such evaluations after certain diagnoses. However, the evidence does not seem to support a need for the proposed mandate.

Most medical experts support the need for primary malignant brain tumor patients to receive a second opinion, even the need to receive a second opinion at a multidisciplinary brain tumor center. But, there is not a consensus that second opinions need to be provided at a Comprehensive Cancer Center. First, not all Comprehensive Cancer Centers have brain tumor centers. Also, staff at NCI and medical experts at several Comprehensive Cancer Centers in the mid-Atlantic region indicated that there are university health systems in Virginia that can provide as high quality second opinion as could be obtained at a Comprehensive Cancer Center. Medical experts in Virginia also emphasized that the critical issue is receiving a second opinion at a multidisciplinary brain tumor center, which may or may not be a Comprehensive Cancer Center.

With regard to gaining access to clinical trials, a concern identified by advocates for the proposed mandate, a review of the clinical trials in NCI's PDQ database indicates that the majority of clinical trials for primary malignant brain tumor patients (70 – 80 percent) take place at centers other than Comprehensive Cancer Centers. Further, Virginia has a clinical trials mandate which, according to both BOI and VAHP, requires insurers to cover patients at out-of-network trials if there is not a comparable trial in network. Insurance plans indicate that, as a result of the clinical trials mandate, they typically cover the initial evaluation to determine eligibility for a clinical trial, which medical experts say is very similar or identical to a second opinion evaluation. However, advocates for the bill cite examples of individuals not receiving coverage for these evaluations. If ensuring that patients have access to clinical trials is a primary concern of advocates, then it appears strengthening the clinical trials mandate (Section 38.2-3418.8, *Code of* Virginia) to ensure that insurance companies cover the initial clinical trial evaluation would more directly address patients' needs.

b. Need Versus Cost

It appears that the cost of the insurance coverage proposed in HB 2156 would be relatively low compared to other mandates due to the small number of people affected by the mandate, the expected low utilization rate, and the modest cost of second opinion evaluations compared to other medical services. This is particularly true if the mandate covers only second opinions. However, it is unclear that the proposed mandate addresses patients' needs. As mentioned previously, not all Comprehensive Cancer Centers have brain tumor centers. Further, it appears that the primary concern of advocates is to allow patients access to clinical trials and investigational treatments. The proposed mandate does not address these needs directly. As mentioned in the previous section, if there is concern that patients are not receiving coverage to determine their eligibility for a clinical trial, then reviewing and strengthen-

ing the clinical trials mandate may more directly address patients' needs.

c. Mandated Offer

Mandated Offer

A mandated offer requires health insurers to offer for purchase the coverage described in the mandate for an additional fee.

A mandated offer would probably not meet the needs for coverage of primary malignant brain tumor patients. Having a primary malignant brain tumor is a relatively rare condition that most people do not anticipate. Further, purchasers of health insurance will probably not consider it critical to seek a second opinion at a Comprehensive Cancer Center.

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Appendix A

Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

§ 2.2-2503. Special Advisory Commission on Mandated Health Insurance Benefits; membership; terms; meetings; compensation and expenses; staff; chairman's executive summary.

A. The Special Advisory Commission on Mandated Health Insurance Benefits (the Commission) is established as an advisory commission within the meaning of § 2.2-2100, in the executive branch of state government. The purpose of the Commission shall be to advise the Governor and the General Assembly on the social and financial impact of current and proposed mandated benefits and providers, in the manner set forth in this article.

B. The Commission shall consist of 18 members that include six legislative members, 10 nonlegislative citizen members, and two ex officio members as follows: one member of the Senate Committee on Education and Health and one member of the Senate Committee on Commerce and Labor appointed by the Senate Committee on Rules; two members of the House Committee on Health, Welfare and Institutions and two members of the House Committee on Commerce and Labor appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; 10 nonlegislative citizen members appointed by the Governor that include one physician, one chief executive officer of a general acute care hospital, one allied health professional, one representative of small business, one representative of a major industry, one expert in the field of medical ethics, two representatives of the accident and health insurance industry, and two nonlegislative citizen members; and the State Commissioner of Health and the State Commissioner of Insurance, or their designees, who shall serve as ex officio nonvoting members.

C. All nonlegislative citizen members shall be appointed for terms of four years. Legislative and ex officio members shall serve terms coincident with their terms of office. All members may be reappointed. However, no House member shall serve more than four consecutive two-year terms, no Senate member shall serve more than two consecutive four-year terms, and no nonlegislative citizen member shall serve more than two consecutive four-year terms. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term. Vacancies shall be filled in the manner as the original appointments. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment.

D. The Commission shall meet at the request of the chairman, the majority of the voting members or the Governor. The Commission shall elect a chairman and a vice-chairman, as determined by the membership. A majority of the members of the Commission shall constitute a quorum.

E. Legislative members of the Commission shall receive such compensation as provided in § 30-19.12, and nonlegislative citizen members shall receive such compensation for the performance of their duties as provided in § 2.2-2813. All members shall be reimbursed for all reasonable and

necessary expenses incurred in the performance of their duties as provided in §§ 2.2-2813 and 2.2-2825. Funding for the compensation and costs of expenses of the members shall be provided by the State Corporation Commission.

F. The Bureau of Insurance, the State Health Department, and the Joint Legislative Audit and Review Commission and such other state agencies as may be considered appropriate by the Commission shall provide staff assistance to the Commission. The Joint Legislative Audit and Review Commission shall conduct assessments, analyses, and evaluations of proposed mandated health insurance benefits and mandated providers as provided in subsection D of § 30-58.1, and report its findings with respect to the proposed mandates to the Commission.

G. The chairman of the Commission shall submit to the Governor and the General Assembly an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

§ 30-58.1. Powers and duties of Commission.

The Commission shall have the following powers and duties:

A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;

B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;

C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;

D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and

E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:

1. Ways in which the agencies may operate more economically and efficiently;

2. Ways in which agencies can provide better services to the Commonwealth and to the people; and

3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

Appendix B

Proposed Mandated Benefit Requiring Coverage of Second Opinion Evaluations for Primary Malignant Brain Tumor Patients at NCI Comprehensive Cancer Centers

HOUSE BILL NO. 2156
Offered January 10, 2007
Prefiled January 9, 2007

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for evaluations of brain tumors.

Patron-- O'Bannon

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for evaluations of brain tumors.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a healthcare plan for healthcare services shall provide coverage for a second opinion evaluation, at a medical center designated by the National Cancer Institute as a comprehensive cancer center, of a brain tumor that has been diagnosed as a primary malignant brain tumor.

B. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed upon all individuals in the same benefit category.

C. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2008, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

D. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, or to policies or contracts designed for issuance

to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

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

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.14~~ *38.2-3418.15*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.09:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13 through 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

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

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

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

Appendix C

Evaluation Topic Areas and Criteria for Assessing Proposed Mandated Health Insurance Benefits

Topic Area	Criteria
1. Medical Efficacy	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit *JLARC Criteria**	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	If the legislation seeks to mandate coverage of an additional class of practitioners: 1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered. 2) The methods of the appropriate professional organization to assure clinical proficiency.
d. Medical Effectiveness of Provider *JLARC Criteria**	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
2. Social Impact	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment *JLARC Criteria**	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	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.
e. Financial Hardship	If the coverage is not generally available, the extent to which the lack of coverage result in unreasonable financial hardship on those persons needing treatment.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

h. Labor Union Coverage	The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.
i. State Agency Findings	Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.
j. Public Payer Coverage *JLARC Criteria**	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact *JLARC Criteria**	Potential public health impacts of mandating the benefit.
3. Financial Impact	
a. Effect on Cost of Treatment	The extent to which the proposed insurance coverage would increase or decrease the cost or treatment of service over the next five years.
b. Change in Utilization	The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.
c. Serves as an Alternative	The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.
d. Impact on Providers	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.
e. Administrative and Premium Costs	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.
f. Total Cost of Health Care	The impact of coverage on the total cost of health care.
4. Effects of Balancing Medical, Social, and Financial Considerations	
a. Social Need/Consistent with Role of Insurance	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.
b. Need Versus Cost	The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.
c. Mandated Option	The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policy holders.

*Denotes additional criteria added by JLARC staff to criteria adopted by the Special Advisory Commission on Mandated Health Insurance Benefits.

Source: Special Advisory Commission on Mandated Health Insurance Benefits and JLARC staff analysis.

Appendix D

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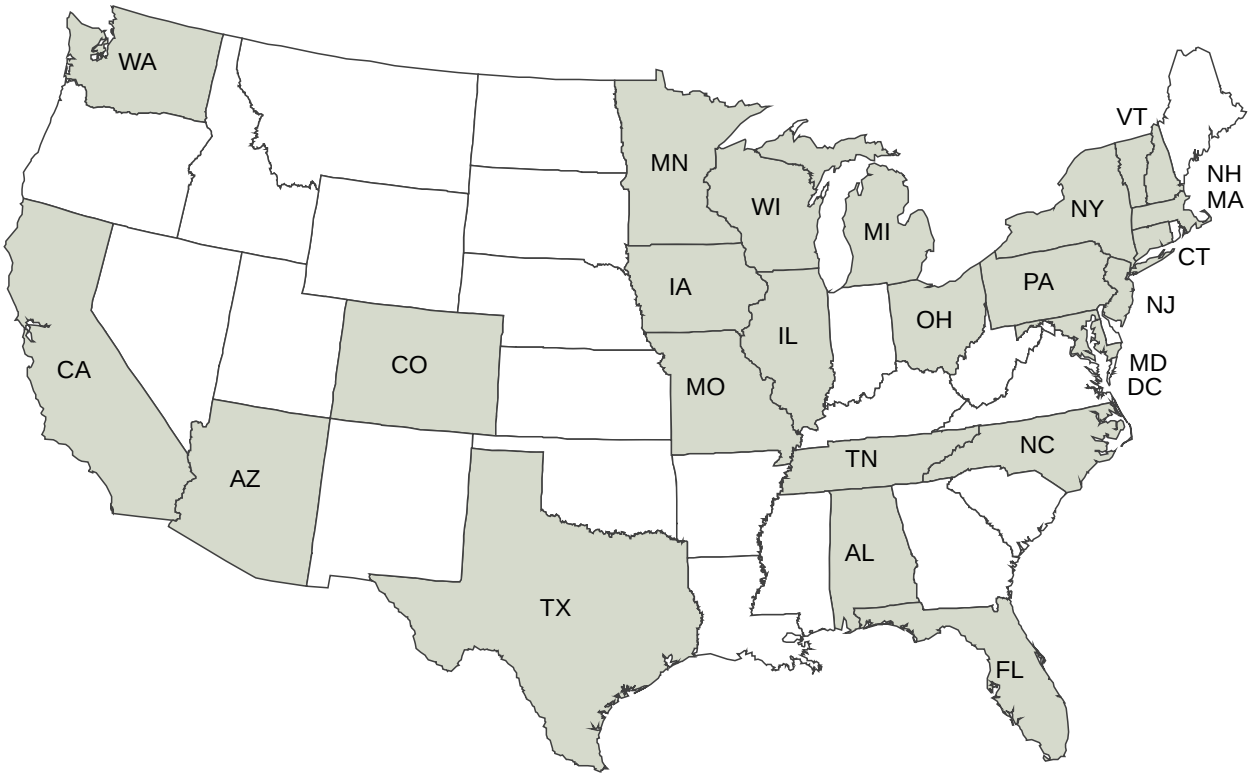
Appendix E

National Cancer Institute Comprehensive Cancer Centers



Note: Shaded states have one or more Comprehensive Cancer Centers. There are none in Alaska or Hawaii.
Source: NCI.

Comprehensive Cancer Center	Location
UAB Comprehensive Cancer Center University of Alabama at Birmingham	Birmingham, AL
Arizona Cancer Center University of Arizona	Tucson, AZ
Chao Family Comprehensive Cancer Center University of California at Irvine	Orange, CA
City of Hope National Medical Center Beckman Research Institute	Duarte, CA
Jonsson Comprehensive Cancer Center University of California Los Angeles	Los Angeles, CA
USC/Norris Comprehensive Cancer Center University of Southern California	Los Angeles, CA

Comprehensive Cancer Center	Location
Rebecca and John Moores UCSD Cancer Center University of California, San Diego	La Jolla, CA
UCSF Comprehensive Cancer Center & Cancer Research Institute University of California San Francisco	San Francisco, CA
University of Colorado Cancer Center University of Colorado at Denver & Health Sciences Center	Aurora, CO
Yale Cancer Center Yale University School of Medicine	New Haven, CT
Lombardi Comprehensive Cancer Center Georgetown University	Washington, DC
H. Lee Moffitt Cancer Center & Research Institute University of South Florida	Tampa, FL
Robert H. Lurie Comprehensive Cancer Center Northwestern University	Chicago, IL
Holden Comprehensive Cancer Center The University of Iowa	Iowa City, IA
The Sidney Kimmel Comprehensive Cancer Center Johns Hopkins	Baltimore, MD
Dana-Farber/Harvard Cancer Center Dana-Farber Cancer Institute	Boston, MA
The Barbara Ann Karmanos Cancer Institute Wayne State University School of Medicine	Detroit, MI
University of Michigan Comprehensive Cancer Center University of Michigan	Ann Arbor, MI
Mayo Clinic Cancer Center Mayo Clinic Rochester	Rochester, MN
University of Minnesota Cancer Center Siteman Cancer Center	Minneapolis, MN
Washington University School of Medicine	St. Louis, MO
Norris Cotton Cancer Center Dartmouth-Hitchcock Medical Center	Lebanon, NH
The Cancer Institute of New Jersey Robert Wood Johnson Medical School	New Brunswick, NJ
Herbert Irving Comprehensive Cancer Center Columbia University	New York, NY
Memorial Sloan-Kettering Cancer Center	New York, NY
Roswell Park Cancer Institute	Buffalo, NY

Comprehensive Cancer Center	Location
Duke Comprehensive Cancer Center Duke University Medical Center	Durham, NC
Wake Forest Comprehensive Cancer Center Wake Forest University	Winston-Salem, NC
UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill	Chapel Hill, NC
Comprehensive Cancer Center The Ohio State University	Columbus, OH
Case Comprehensive Cancer Center Case Western Reserve University	Cleveland, OH
Abramson Cancer Center University of Pennsylvania	Philadelphia, PA
Fox Chase Cancer Center	Philadelphia, PA
University of Pittsburgh Cancer Institute	Pittsburgh, PA
Vanderbilt-Ingram Cancer Center Vanderbilt University	Nashville, TN
M.D. Anderson Cancer Center University of Texas	Houston, TX
Vermont Cancer Center University of Vermont	Burlington, VT
Fred Hutchinson/University of Washington Cancer Consortium Fred Hutchinson Cancer Research Center	Seattle, WA
UW Paul P. Carbone Comprehensive Cancer Center University of Wisconsin	Madison, WI

Joint Legislative Audit and Review Commission
Suite 1100
General Assembly Building
Capitol Square
Richmond, Virginia 23219
804-786-1258 Fax 804-371-0101
http://jlarc.state.va.us