

REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

**HOUSE BILL NO. 1405:
MANDATED COVERAGE OF TREATMENT FOR
INTENSITY MODULATED RADIATION
THERAPY (IMRT) FOR TUMORS**

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2007

January 8, 2007

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 1405 regarding a proposed mandate coverage of treatment for intensity modulated radiation therapy for tumors.

Respectfully submitted,

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

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MANDATED HEALTH INSURANCE BENEFITS

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INTRODUCTION

The House Committee on Commerce and Labor referred House Bill 1405 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2006 Session of the General Assembly. House Bill 1405 was introduced by Delegate Robert J. Wittman.

The Advisory Commission held a hearing on October 17, 2006 in Richmond to receive public comments on House Bill 1405. In addition to the patron, Delegate Robert J. Wittman, four doctors and a medical physicist spoke in favor of the bill. Written comments in support of the bill were provided by the American College of Radiation Oncology, Associates in Medical Physics, Bethesda Regional Cancer Treatment Center, Comprehensive Physics and Regulatory Services, Ltd., Congressional Representative Jo Ann Davis, the County of Lancaster, Eastern Virginia Medical School Department of Radiation Oncology and Biophysics, Farmington Regional Radiation Therapy Services, Hematology-Oncology Associates of Fredericksburg, Inc., Mountain Regional Cancer Centers, Senator John H. Chichester, 21st Century Oncology, the Town of Montross, the Town of Warsaw, University of Louisville Health Science Center, Valley Regional Cancer Center, Virginia Cancer Institute, Westmoreland County Board of Supervisors, and eight concerned citizens. A representative from the American Cancer Society (ACS) also commented on House Bill 1405. Representatives from the Virginia Association of Health Plans (VAHP) and Anthem Blue Cross Blue Shield spoke against House Bill 1405. The VAHP and the Virginia Chamber of Commerce (VCC) submitted comments in opposition to the bill.

The Joint Legislative Audit and Review Commission (JLARC) provided a report on the evaluation of House Bill 1405: Mandated Coverage of Intensity Modulated Radiation Therapy (IMRT) for Specified Cancer Sites in accordance with sections 2.2-2503 and 30-58.1 of the Code of Virginia. The report is available on the JLARC website at <http://jlarc.state.va.us>.

SUMMARY OF PROPOSED LEGISLATION

House Bill 1405 adds § 38.2-3418.15 to the Code of Virginia. The bill requires insurers 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; corporations providing individual or group accident and sickness subscription contracts; and HMO's providing health care plans for health care services to provide coverage for treatment by intensity modulated radiation therapy (IMRT), including solid compensator-based IMRT, of breast cancer, brain tumors, prostate cancer, lung cancer, bladder cancer, cancer of the pancreas and other upper abdominal sites, spinal cord tumors, head and neck cancer, adrenal tumors, pituitary tumors, and other solid tumors in situations in which extremely high precision is required in order to spare essential

surrounding normal tissue, when such treatment is performed pursuant to protocol dose volume constraints approved by the institutional review board of any United States medical teaching college or the National Cancer Institute (NCI).

The bill prohibits insurers, corporations, or HMOs from imposing copayments, fees, policy year or calendar year, or durational benefit limitations or maximum on persons for these benefits or services that are not equally imposed on all individuals in the same benefit category.

The bill applies to insurance policies, contracts, or plans delivered, issued for delivery, reissued, or extended in the Commonwealth on or after July 1, 2007, or at any time thereafter when the term is changed or a premium adjustment is made. The bill does not apply to short-term travel, accident-only, limited or specified disease policies, or individual conversion policies, or contracts designed for persons eligible for coverage under Title XVIII of the Social Security Act (Medicare), or any other similar coverage under state or federal government plans.

Intensity Modulated Radiation therapy

According to Varian Medical Systems (Varian), cancer cells have a predisposition to grow and divide more rapidly than normal cells. High doses of radiation have proven to be effective in killing the cancer cells or shrinking the tumors. Varian introduced a wholly integrated high-resolution IMRT solution called SmartBeam™ IMRT. Varian explained that the IMRT modulates the intensity of the radiation of X-rays to be used as therapy for cancer.¹



According to Varian, the development of IMRT was achieved by three major inventions during the past 15 years including: the digital linear accelerator (linac) for generating high-energy treatment X-rays in a very accurate way; the computer-controlled multileaf collimator (MLC) for shaping the radiation beam; and the sophisticated “inverse” treatment planning software programs.² In 2001, Varian noted that IMRT was one of the newest forms of radiation therapy that draws on computer-generated images to plan and then deliver more tightly focused radiation beams to cancerous tumors than with conventional radiation.³

The 2003 Trinity Health report, entitled “Emerging Trends and Technologies, Intensity-Modulated Radiation Therapy” stated that IMRT was developed through the 1990s to produce beams of varying intensity to target three-dimensional tumor volumes. The report stated that IMRT utilizes multiple x-ray beams to precisely treat localized cancer through the usage of a multi-leaf collimator while diminishing the radiation exposure of surrounding healthy tissues. It was reported that the accuracy of the procedure in avoiding normal tissue along with the ability to increase dosage to tumor volume has produced superior outcomes for certain types of cancer. A number of experts believe that IMRT might be the ideal treatment option for approximately 20 to 30 percent of radiation therapy cases.⁴

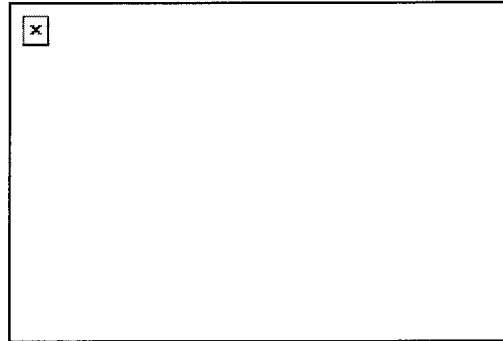
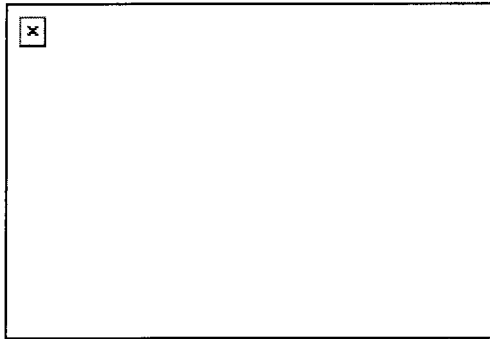
The Mayo Foundation for Medical Education and Research stated that the three-dimensional conformal radiation therapy (3-D CRT) is a more standard radiation therapy that uses diagnostic imaging, computers and special software to conform the radiation beam to the shape of the tumor. The IMRT is the latest advance in 3-D CRT technology. The intensity of the IMRT includes hundreds of small radiation beams to produce dosage distributions that are more precise (conformal) than those possible with 3-D CRT.⁵

The Mayo Clinic article highlighted the advantages of IMRT compared to the traditional radiation therapies that include decreasing the radiation to normal surrounding sensitive tissues, decreasing the chance of harming normal cells, producing a higher radiation dosage with precise distribution to cancer cells, and increasing the chance of destroying cancer cells.⁶ The article stated that IMRT is a powerful cancer fighting technology and a revolutionary radiation therapy. The treatment is able to shape the radiation beams to the size, shape and location of the tumor while minimizing radiation exposure to surrounding healthy tissues or organs.⁷

The Mid-Rivers Cancer Center considers IMRT one of the most advanced radiation systems in destroying cancer cells without damaging normal tissues. IMRT is a state-of-the-art treatment that allows radiation therapists the capability to “sculpt” the edges of a tumor, delivering radiation to a tumor with more precision and accruing, sparing the adjacent healthy tissues, and resulting in fewer side effects.⁸ The Mid-Rivers Cancer Center State of the Art Facility consists of:

Megavoltage Linear Accelerator:

Computerized Tomography (CT) Simulator:



The Mid-Rivers Cancer Center emphasized that this type of radiation treatment has opened the doors to patients that may have been previously unsuccessful candidates for radiation because the tumors were located near vital organs.

The Trinity Health report stated that there are multiple methods of producing intensity-modulated beams and that each method utilizes different types of equipment and results in unique benefits and risks including:⁹

IMRT Production Options	Merits of Each IMRT Type
Metal Compensators	The metallic compensator is customized to create a specific beam thickness. This method has several limitations: it is expensive and time consuming and the compensators are heavy, limiting the number of beams that can be delivered.
Multiple Segments per Field or "Step and Shoot"	This method of IMRT delivery can occur in systems using 3D-CRT. To produce the conformality many additional segments are added to the beam. While this method may limit required capital expenditure, the time for treatment may be longer than other types of IMRT.
Dynamic MLC (dMLC) or "Sliding Window"	This method uses pairs of moving MLC leaves. The delivery time is significantly faster, however a downside is the risk of radiation leakage between MLC leaves. An enhanced method of dynamic MLC is intensity modulated arc therapy that has similar quick treatment times.
Tomotherapy	This IMRT technique irradiates the target slice by slice. An example of this technique is the multivane intensity modulating collimator (MIMiC) that attaches to the head of the linear accelerator. Accurately positioning the patient is a key as misalignment of the slices can lead to under or over dosing.
Helical Tomotherapy	This system combines treatment planning, patient positioning, and treatment delivery. Helical tomotherapy uses a spiral delivery pattern that circles the patient. The combination with CT allows for continual quality assurance checks. With only one manufacturer and recent Federal Drug Administration approval, the helical tomotherapy is expensive.

The Trinity Health report noted that institutions are moving toward Dynamic Multi-leaf Collimator and Tomotherapy systems with Helical Tomotherapy gaining recognition as the optimal technique.¹⁰

The publication titled “Medicare Learning Network Matters” from the Centers for Medicare & Medicaid Services (CMS) stated that IMRT is also known as conformal radiation that delivers radiation with adjusted intensity to protect adjoining normal tissue. The two methods by which IMRT can be delivered to cancer patients include the MLC and the compensator-based IMRT.¹¹ The Mid-Rivers Cancer Center explained the solid brass compensator, an essential component of the IMRT, is an attachment for the front of the linear accelerator (the radiation treatment machine) that molds the beams to conform to the 3-dimensional shape of the tumor. The solid brass compensator moves during the delivery of the beam that will customize the radiation dosage to different areas of the patient’s tumor.¹²

Varian stated that the course of medical treatments by SmartBeam IMRT consists of three basic steps including diagnosis, treatment planning and delivery. During the diagnostic stage, the physician generates three-dimensional diagnostic images of the patient’s anatomy and then determines the dose of radiation. In some cases, treatment planning includes a simulation session to further pinpoint the cancer and to finalize the radiation treatment plan.¹³

A radiation oncologist prescribes the type and amount of treatment that best satisfies a patient’s needs. The oncologist works closely with a highly trained health care team that includes (i) a radiation physicist that participates in the planning process and guarantees that the machines deliver the right dose of radiation; (ii) a dosimetrist that plans the treatment with the oncologist and the physicist; (iii) a radiation therapist that sets the patient up for treatment and monitors the equipment in delivering the radiation; and (iv) a radiation therapy nurse that provides nursing care including helping patients become knowledgeable about the treatment and assisting the patients with any side effects.¹⁴

According to an editorial by the Radiology Society of North America Inc., IMRT is an assertive therapy that requires multiple treatment sessions. An oncologist reviews the patient’s health, prescribes the type of treatment, and examines the location and size of the malignant tumor. Patients are normally scheduled for an IMRT session five days a week for approximately six to ten weeks and each treatment usually takes between 15 and 30 minutes. It was explained that IMRT is painless and when a patient starts to feel sick or becomes uncomfortable, the treatment from the machine can be stopped. Some patients may experience treatment related side effects during the treatment process. The nature of the side effects will depend on the normal tissue structures being irradiated.¹⁵

The Trinity Health report stated that although IMRT has been available for almost a decade, acceptance throughout the country has been comparatively

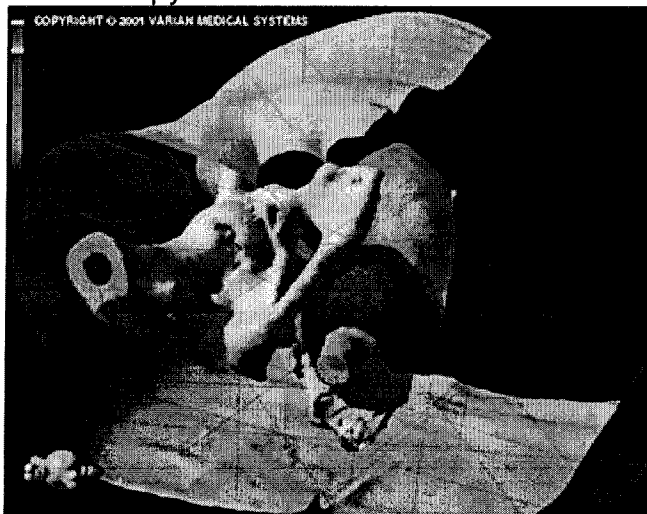
slow until the past couple of years. The report stated that “the implementation is gaining force due to several factors including: clinical evidence reveals IMRT’s qualities and merits in treating certain cancers; newer IMRT system generates more user-friendly interfaces that assist in training and confidence; and consumer education of cancer treatment options increases the demand for IMRT.”¹⁶

SOCIAL IMPACT

As of April 2002, the Trinity Health report stated that there were 157 IMRT programs operating in the United States. The Health Care Advisory Board projected an additional 500 to 550 providers would begin offering IMRT by Spring 2003. The 2002 survey reported that approximately 32.1 percent of radiation oncologists used IMRT and that approximately 97.2 percent of current nonusers are planning to implement IMRT in the future.¹⁷

The Trinity Health report further stated that Memorial Sloan-Kettering Cancer Center uses IMRT to treat 80 children per year with sarcomas, brain tumors, muscle tumors, and cancer of the head and neck. The Sloan-Kettering Cancer Center explained that the process of dispensing IMRT treatment is particularly labor intensive for children; however the center is providing opportunities to care for children that would otherwise be without treatment alternatives.¹⁸

In September 2003, Chippenham Johnston-Willis (CJW) Medical Center began treating its cancer patients with IMRT. At that time, radiation oncologists at CJW considered IMRT the most significant advancement tool in the medical field in the past 50 years. Dr. Thomas Eichler, Director of Radiation Oncology, stated that “IMRT allows physicians to customize a patients’ treatment to the size, shape and location of their tumor with greater accuracy compared to conventional radiation therapy”.¹⁹



Pictured above, a plan for treating prostate cancer with IMRT concentrates the radiation dose in the tumor (red) while avoiding the nearby bladder (yellow) and rectum (green).

The Thomas Johns Cancer Center at Johnston-Willis Hospital, Department of Radiation Oncology provides annual services for over 700 new patients and delivers thousands of radiation treatments.²⁰

The article, “Northern Neck Clinic Struggles to Stay Open”, dated February 13, 2006 in the Richmond Times-Dispatch, stated that the sole purpose for opening the radiation oncology center in the rural Northern Neck area was to provide cancer therapy for the residents that were struggling for survival. The Virginia Department of Health reported that 303 residents in Westmoreland County died of cancer from 1998 to 2002, a rate of 266.7 deaths per 100,000 individuals compared to the entire state that experienced an incidence rate of 204.8 cancer deaths per 100,000 individuals.²¹

The American Cancer Society’s website provided a Virginia Cancer Incidence report for the period between 1999 through 2003 based on information from the 2006 Virginia Cancer Registry (VCR). During that time period, 147,579 cancer cases were reported in Virginia at a rate of 428.1 per 100,000 persons. The following data was included.²²

Categories	Female		Male		Both Genders	
	Case	Rate	Case	Rate	Case	Rate
Breast	23,485	122.6				
Cervical Cancer	1,437	7.6				
Colorectal Cancer	8,290	43.2	8,494	58.5		
Lung and Bronchus	9,280	48.9	12,274	83.8		
Melanoma (Skin)					5,415	15.3
Prostate Cancer			24,391	162.1		

In July 2006, the VCR provided a distribution report on the number of selected cancers receiving IMRT treatment in Virginia. It was noted that cancer data in the VCR reflect a conservative account of the disease and that some areas in Virginia may have been underreported. The VCR reported that from 2001 to 2003 the following categories and number of cancer tumors were treated by IMRT: 33 counts of oral cavity and pharynx, 120 counts for prostate, 34 counts for head and neck, 79 counts for all breast, and 79 counts for female breast.²³

The article, “Neck Cancer Center Pained”, dated April 30, 2006 in the Free Lance-Star, stated that according to Dr. Christopher S. Walsh, Medical Director of the Mid-Rivers Cancer Center, coverage changes by Medicare and Anthem would affect approximately thirty three percent of the patients.²⁴

FINANCIAL IMPACT

The Trinity Health report discussed several major equipment components that are required for IMRT.²⁵

Equipment	Purpose	Cost
Linear Accelerator (LINAC)	Delivers radiation beams	Full system (Including multi-leaf collimator): \$1.5 - million
Multi-leaf Collimator	Used to shape radiation beams to allow for customized intensity	As a retrofit: \$425,000
Treatment Planning System	Computerized system for inverse treatment planning, allows more precision to clinician objectives	\$75,000 - \$125,000, if basic treatment planning software and IS infrastructure is unavailable costs can be much higher.
Auto Field Sequencing	Provides exchange of data between IMRT components	\$40,000
Quality Assurance Software	Portal imaging verifies that beams are delivered as planned	\$25,000

The Trinity Health report indicated that a representative of St. Luke's Cancer Center in Bethlehem, Pennsylvania reported payments for a course of 37 conventional radiation oncology treatments at \$100 each (\$3,700) as compared to 37 IMRT treatments at \$400 each (\$14,800). The report noted that many hospitals are implementing IMRT programs but that some areas of the country are still without providers.²⁶

An article, "Neck Cancer Center Pained" reported that IMRT is more expensive than 3-D conformal radiation treatments. The Mid-Rivers Cancer Center in Montross, Virginia received approximately \$617 per treatment IMRT. The article reported that treatment for some breast cancer patients that include 26 IMRT sessions may cost approximately \$16,000 compared to \$82 per treatment for 3-D conformal treatments which would total \$2,100.²⁷

MEDICAL EFFICACY

The medical efficacy of IMRT continues to be discussed by medical professionals. The 2003 Trinity Health report noted that one of the most important goals of IMRT includes sparing the normal tissue by reducing the toxicity to surrounding areas, this minimization of peripheral damage permits IMRT to improve cancer control and cure by delivering intensified doses to the targeted areas of tumor.²⁸ The report explained that the clinical outcomes do show that for certain categories of cancer these goals are attained. Despite the promise of IMRT, some clinicians remain skeptical. The report stated:

Many agreed that additional information regarding IMRT's applicability to various cancer types is needed, as extrapolation of current research on prostate and head and neck cancer is not necessarily accurate due to the uniqueness of different cancers. A common technical concern is that the close tailoring could leave peripheral sections of the cancerous tumor untreated. Apprehension also exists as IMRT appears to be more sensitive to geometric uncertainty in defining the target area, which is important due to the propensity for target movement and the use of dose gradients. Other believed IMRT increases the risk of developing secondary cancers due to the potential for greater leakage of radiation and longer beam on times that may increase whole body radiation exposure. Eli Glatstein of the University of Pennsylvania Medical Center exerts that this "greater whole-body dose leads to a predictable increase in radiation-induced neoplasms, especially leukemia." Many clinicians believed additional outcomes research is needed to address the impact of IMRT on various cancer types as well as the long-term health effects of IMRT.²⁹

Radiation oncologists at the Mayo Clinic consider IMRT to be ideal for patients diagnosed with prostate cancer in addition to benign and malignant tumors of the head and neck, and other organs that lie near important body parts including the eyes, optic nerves, brain, brain stem, salivary glands, bladder, rectum, small bowel, kidneys, liver, lung and spinal cord. The oncologists have treated more than 200 patients annually at the clinic with IMRT.³⁰

The North Shore Medical Accelerator was one of the first centers on Long Island in New York to use IMRT in 1994. The center has treated its patients with IMRT for tumors in the head and neck, brain, prostate, breast, kidney, esophagus, lung, extremity, spine, abdomen, and cervix. The center stated that improvements in clinical outcomes have been realized while minimizing the side effects that would have been expected with alternative conventional techniques. Side effects may include spinal cord dysfunction, chronic dry mouth (xerostomia), damage to the bladder and rectum in prostate cases. IMRT is also used to treat patients with recurrent cancers or untreatable tumors that have already received the maximum amount of radiation allowed by conventional means.³¹

A study by Claus and Associates (2001) examining the use of IMRT for the treatments of patients with ethmoid sinus tumors was included in the policy bulletin of one insurer. The study noted that IMRT has the potential to save binocular vision because the dose to the optic pathway structures can be reduced selectively by this process. The National Comprehensive Cancer Network (NCCN) 2003 guidelines on prostate cancer identified IMRT as an alternative to 3-D conformal radiation therapy for ultra-high dose (dosage of 75 Gy or more) radiation treatment of prostate cancer. It was stated that IMRT is not routinely indicated in breast cancer and that evidence at that time was primarily limited to descriptive studies, evaluations of technical feasibility, and

dosimetric planning studies. There was a scarcity of evidence from clinical outcome studies, and no clinical outcomes studies directly compared the effectiveness of IMRT to 3-D conformal radiation therapy for breast cancer.³²

The 2003 Trinity Health report stated that pediatric patients benefit tremendously from IMRT treatments because children are particularly exposed to damage of developing normal tissues by radiation therapy. IMRT minimizes the radiation field to protect these developing areas while at the same time providing a dose high enough to fight strong structures of cancer. Concerns about treating pediatric patients with IMRT include the risk of increased radiation dose to the entire body, increased difficulty with patient's immobilization that may require anesthesia in younger children, and long-drawn-out treatment planning.³³

On November 2005, Anthem Professional Forum reported that Anthem Blue Cross and Blue Shield in Virginia implemented a change in the medical coverage guideline regarding IMRT that was effective on April 1, 2006. The guideline stated that IMRT is considered medically necessary for the following conditions:

Inpatients with non-metastatic prostate cancer for dose escalation > 75 Gy, inpatients with head and neck cancer, particularly the naso-pharyngeal carcinoma and disease at the unilateral base of the tongue and tonsil, and limited neck lesions; and patients with central nervous system (CNS) lesions in close proximity to the optic nerve or brain stem. The guidelines concluded that IMRT is considered investigational in all other types of cancer, including but not limited to lung, breast, and abdominal cancer and cancer of unknown primary origin. It was also noted that IMRT is not medically necessary in patients receiving brachytherapy.³⁴

In 2005, Blue Cross Blue Shield Association Technology Evaluation Center performed an assessment and concluded that available data was insufficient to determine whether IMRT is better-quality to 3-D conformal radiotherapy for improving health outcomes of patients with lung cancer. The assessment acknowledged no studies that directly compared health outcomes of IMRT with health outcomes of 3-D conformal radiotherapy for lung cancer, using concurrent or historical controls.³⁵

One insurer referenced the National Cancer Institute, 2005 Guidelines in its comments on the bill on the use of IMRT in clinical trials. The guidelines stated:

IMRT is still a nascent technology. Currently, most published reports on the clinical use of IMRT are single institution studies, and are either treatment planning studies for a limited number of cases showing the improvement in dose distributions generated by IMRT, or dosimetric studies confirming IMRT treatment. There are no published reports at present of prospective randomized clinical

studies involving IMRT, and this lack of information clearly limits our knowledge of the effect of the use of IMRT on clinical outcomes. The guidelines discussed some concerns regarding IMRT including the potential to miss a tumor, or at least underdose a portion of the tumor, to have significant high dose volumes in the normal tissues, and that the widespread use of IMRT could lead to an increased incidence of radiation therapy associated carcinomas due to the larger volume of normal tissue exposed to low doses and the increase in whole body doses as a result of the increased doses of radiation required for delivery of IMRT.³⁶

According to the article, "Neck Cancer Center Pained", as of January 1, 2006, TrailBlazer Health Enterprises, administrator for the federal Medicare program, noted that treatment of IMRT is appropriate when the location of the tumor is close to a vital organ that may be dangerous or be possible harm during treatment that requires a high dosage of radiation. The article stated that Medicare patients in Virginia will receive coverage for cancer treatments of the central nervous system, head and neck, prostate, lung or pancreas. However, patients that have been diagnosed with breast cancer and colon cancer will receive 3-D conformal radiation if they want Medicare to pay for their coverage. It was noted that exceptions are made if the patients' doctor states that IMRT is medically necessary.³⁷

The article, "Intensity-Modulated Radiotherapy in the Standard Management of Head and Neck Cancer: Promises and Pitfalls" dated June 10, 2006 stated some of the disadvantages associated with IMRT include "increased risk of a marginal miss, decreased dose homogeneity, increased total body dose, and increased labor and expense. Outcomes data after IMRT are limited, and follow-up is relatively short."³⁸

A proponent provided two abstracts relating to the efficacy of IMRT to the Advisory Commission. The first abstract was "Abstract Plenary 1: Phase III Randomized Study of Intensity Modulated Radiation Therapy Versus Standard Wedging Technique for Adjuvant Breast Radiotherapy." The objective of the study was to evaluate if breast intensity modulated radiation therapy (BIMRT) translates into a reduction in acute skin toxicity compared to WC. The study included 331 patients in its analysis. The abstract reported that "BIMRT significantly improves dose distribution homogeneity and particularly the hot-spot to the breast crease." The study concluded that "compared to the standard wedge compensation radiation treatment, BIMRT significantly reduces the development of server moist desquamation." The study recommended BIMRT for adjuvant radiotherapy of breast cancer.³⁹

The second abstract was "Abstract 1079: Intensity Modulation Radiation Therapy Results in a Significant Decrease in Clinical Toxicities When Compared

to Conventional Wedge Based Radiation Therapy.” The objective of the study was to determine if IMRT results in a benefit in clinical outcomes. The study included 172 patients in the analysis. The study concluded:

Improved dose distribution with the use of IMRT in the treatment of whole breast results in a significant decrease in acute dermatitis, edema, and hyperpigmentation as well as a reduction in the development of chronic breast edema compared to conventional wedge based radiation treatment.⁴⁰

FEDERAL REQUIREMENTS FOR IMRT TREATMENT

According to the CMS, IMRT uses computers to modify the intensity of the beam across each individual field by the use of moving collimators. The conventional treatment with MLC makes use of the positions of the collimator leaves, while IMRT makes available the dynamic motion of the various collimator leaves during each session of therapy. The CMS stated that IMRT is not a replacement therapy for conventional and 3-D conformal radiation therapy methods in every situation.⁴¹ IMRT is designed to treat tumors that are located close to the vital organs and structures, and if those adjacent structures would be considerably exposed to collateral damage using conventional techniques. IMRT is mainly used to treat irregular shaped tumor volumes and to provide high-dose treatments of tumors when the location is next to normal organs that would otherwise have prohibited that higher dose treatment. CMS stated:

No randomized trials currently support specific indication of IMRT, and coverage will be applied to neoplasms that have shown benefit based on use and research from Centers of Excellence. IMRT is an acceptable modality and assumed medically necessary for the treatment of the following conditions including: primary malignant lesions of the central nervous system, secondary malignant neoplasms of the central nervous system, primary benign lesions of the central nervous system, malignant lesions of the head and neck (excluding skin lesions) malignant lesions of the prostate, unresectable retroperitoneal sarcoma and extremity sarcoma, lung cancer and upper abdominal/peri-diaphragmatic (hepato-biliary or mesothelioma) cancers that have unacceptable motion with breathing, pancreatic and adrenal tumors.⁴²

Medicare does not cover the routine use of IMRT including breast cancer, colon cancer and metastatic cancer to the vertebral bodies. However, IMRT may be still considered reasonable and necessary with supporting medical documentation when at least one of the following justifying conditions exists:

Vital organs and structures that are in close proximity such that accuracy and extremely high precision are required beyond that available with conventional radiation therapy. IMRT may be

considered reasonable and necessary when the Dose Volume Histogram shows the necessity to protect at least three critical structures, tumor volume has been previously irradiated and immediately adjacent portals must be established with high precision, Gross Tumor Volume (GTV) margins are irregular and in close proximity to critical structures that must be protected to avoid unacceptable morbidity, only the IMRT method would decrease the probability of grade 2 or grade 3 radiation toxicity compared to conventional radiation in more than 15 percent of radiated similar cases.⁴³

The CMS coverage policy requires that the IMRT treatment plan must be made available on request. The documentation requirements include a concise summary of dosimetry for the entire course of IMRT treatment that is created jointly by the physicist and the physician. The summary should also outline the individual specific parameters of the IMRT treatment.⁴⁴

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty-three companies responded by September 12, 2006. Eight insurers indicated that they have little or no applicable health insurance business in force in Virginia and, therefore could not provide the information requested. Of the 35 respondents that completed the survey, 21 insurers reported that they provide coverage for IMRT but only in certain instances and 10 insurers reported that they currently provide coverage as proposed by House Bill 1405. Four insurers reported that they do not provide coverage as required by House Bill 1405.

Five respondents to the Bureau of Insurance survey provided cost figures that ranged from less than \$.36 to \$15.58 per month per standard individual policyholder to provide coverage required by House Bill 1405. Twenty-one respondents reported cost figures that ranged from \$0.00 to \$13.81 per month per standard group certificate. Four insurers that estimated the cost of providing coverage on an optional basis provided cost figures of \$.90 to \$4.00 per month per individual policyholder. Fifteen insurers provided cost figures for coverage required by House Bill 1405 on an optional basis of \$0.00 to \$22.53 per month per group certificateholder. One respondent reported \$431.25 for the monthly cost of its total policy premium and did not supply an estimate or cost for each bill.

Four companies stated that coverage for IMRT for breast and lung cancer was removed from their standard benefits effective April 1, 2006.

Two companies stated that they provide coverage for IMRT for treatments to the brain, head, neck, spine, paraspinal regions, prostate, and breast.

Two companies stated that they provide coverage of IMRT treatment for brain tumors, prostate cancer, and head and neck cancers. They noted that other procedures would have to be reviewed medically on a case by case basis.

Two companies stated that they do not provide coverage as required by House Bill 1405 however; they do provide coverage of IMRT for head, neck, and prostate cancer deeming the other uses of IMRT experimental and investigational.

Two companies stated that they currently provide coverage for modular radiation therapy for tumors based on the company's coverage position defined under radiology. The companies stated that their radiology benefits are broader than the requirements in House Bill 1405.

Two companies stated that they currently provide coverage of IMRT for prostate cancer.

Four companies stated that their policies do not cover IMRT in instances where it is experimental.

SIMILAR LEGISLATION IN OTHER STATES

According to information published by the National Association of Insurance Commissioners, no states mandate coverage for treatment by IMRT for tumors. However, many health insurance policies do provide coverage for radiation therapy.

REVIEW CRITERIA

SOCIAL IMPACT

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

The Virginia Department of Health reported that 303 residents in Westmoreland County died of cancer from 1998 to 2002, a rate of 266.7 deaths per 100,000 individuals compared to the entire state that experienced an incidence rate of 204.8 cancer deaths per 100,000 individuals.⁴⁴

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Colorectal Cancer	8,290	43.2	8,494	58.5		
Lung and Bronchus	9,280	48.9	12,274	83.8		
Melanoma (Skin)					5,415	15.3
Prostate Cancer			24,391	162.1		

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

In a 2006 State Corporation Commission Bureau of Insurance survey of the fifty top writers of accident and sickness insurance in Virginia, 35 companies currently writing applicable business in Virginia responded. Of the 35 respondents that completed the survey, 21 insurers (60%) reported that they provide coverage for IMRT but only in certain instances and 10 insurers (29%) reported that they currently provide coverage as proposed by House Bill 1405.

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.*

Mid-Rivers Cancer Center stated that Virginia's Northern Neck is a federally designated medically underserved region. It is a rural area with comparatively low household income levels and higher than average cancer rates. In addition, cancer patients in the Northern Neck generally have more advanced cancer than patients in regions with better access to care. As a result, their treatment is often more complex, requiring more extensive target coverage, which drives the requirement for more extensive radiation shielding. Patients rely on insurance companies to protect them when they have a catastrophic illness. Without insurance coverage, most patients will be unable to afford IMRT.⁴⁶

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.*

Mid-Rivers Cancer Center stated that without insurance coverage, IMRT is simply out of reach for most of the population of lung cancer or breast cancer

patients in the Northern Neck. Dr. Walsh testified at the public meeting that many residents had very limited medical options to choose from regarding cancer treatments. Mid-Rivers Cancer Center explained that the cancer patients cope with traveling a great distance to receive medical care in conjunction with other medical bills that usually incurred in any cancer treatment.⁴⁷

Trinity Health reported payments for a course of 37 conventional radiation oncology treatments at \$100 each (\$3,700) as compared to 37 IMRT treatments at \$400 each (\$14,800).⁴⁸

The article, *Neck Cancer Center Pained* article reported that IMRT is more expensive than 3-D conformal radiation treatments. The Mid-Rivers Cancer Center received approximately \$617 per treatment IMRT. The article reported that treatment for some breast cancer patients that include 26 IMRT sessions may cost approximately \$16,000 compared to \$82 per treatment for 3-D conformal treatments which would total \$2,100.⁴⁹

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

Ten proponents signed up to testify in favor of House Bill 1405. There were numerous people in the audience that stood to show their support of the bill at the public meeting. Five speakers testified at the public hearing in support of House Bill 1405. A physician stated that IMRT is the only life-saving option for certain kinds of aggressive tumors. When doctors are using other forms of radiation therapy, they cannot deliver enough radiation to aggressive tumors without damaging the surrounding organs and tissues. IMRT provides a customized shield to protect the surrounding tissues and organs. The physician introduced a patient that underwent radiation therapy with IMRT after being previously treated with conventional radiation. The physician was able to spare a portion of the patient's breast that had been previously irradiated. He asserted that the only way to treat the patient was using the intensity modulator approach and that the patient's cancer nearly disappeared during the course of the IMRT treatments. One proponent stated that the outcomes of the patients that have been treated are generally recognized as being superior to those treated with conventional radiation therapy.⁵⁰

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

Four physicians testified in favor of House Bill 1405 at the public hearing. One stated that IMRT is the single most important advance in radiation oncology. Dr. Mills stated that IMRT is the only option for some patients and that it should not be limited to only a few treatment sites. He noted that when patients receive less than optimal treatment with conventional radiation therapy and receive radiation to normal tissues, the unfortunate result will make greater demands on the health care system in the long-term. Dr. Mills concluded that IMRT is not

investigational or experimental but, a refinement of proven therapy. Dr. Mills was responsible for planning 1,000 IMRT treatments for patients. He stated that about 15% of his patients, including 5% of breast patients and 10% of lung patients have been treated with IMRT.⁵¹

A medical physicist testified that IMRT is not experimental but rather a refinement of existing techniques. The physicist explained that IMRT greatly reduces the peripheral dose to surrounding tissues and organs and that the patients can expect maximum curative effect.⁵²

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

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contract is unknown.

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.

The Advisory Commission is not aware of any findings of the state health planning agency or health system agency relating to the social impact of treating individuals for tumors with IMRT. However, in 2004, Mid-Rivers Cancer Center, LLC., requested a certificate of public need (COPN) to develop a new radiation therapy service that would be located in Montross, VA in Westmoreland County in planning district (PD) 17 Northern Neck. The Eastern Virginia Health Systems Agency, Inc. (EVHSA) Board of Directors recommended to the Commissioner of the Virginia Department of Health (VDH) that the request be approved for the following reasons:

The proposed project appears to be substantially consistent with the relevant components of the State Medical Facilities Plan; the proposed project would substantially improve the geographic access to radiation therapy for the residents of PD 17, a number of residents of PD 16 and 18, and southern Maryland; the proposed project is not anticipated to have a negative impact on the utilization, costs, or charges of any other provider of radiation therapy services in HPR V, the Richmond area, or Fredericksburg; and there do not appear to be any less costly or more effective alternatives to the proposed project if the geographic access to radiation therapy services is to be improved for residents of PD 17.⁵³

As required by Section 32.1-1102.3B of the Code of Virginia, the VDH reviewed all the factors that must be taken into account for determining a public

template-driven and planned primarily by non-physicians. Most payers currently provide reimbursement of IMRT for prostate cancer.⁵⁶

No information was provided by proponents or opponents that would indicate that House Bill 1405 would increase or decrease the cost of treatment over the next five years.

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

The appropriate use of IMRT might increase if the technology and insurance coverage are more readily available. Mid-Rivers Cancer Center believes that IMRT is the best way to increase the effective dose of radiation within a tumor target while constraining and restricting the dose to non-target tissues. In the rural Northern Neck, access to specialty care is limited and the cancer incidence and death rates are higher than the state average.⁵⁷

The ACS stated that although it is clear that the use of IMRT is not necessary for all patients undergoing radiation treatment, there are general and individual situations where IMRT can provide patients outcome benefits. IMRT should be a tool available to the radiation oncologist to use when needed and should not be restricted. ACS explained that the ambiguous definition of IMRT and the issues surrounding its reimbursement have been a source of complication but this should not stand in the way of providing optimal patient care. To support this mandate, however, as written may result in difficulties with excessive use of this highly reimbursed technology.⁵⁸

Written comments from the VAHP stated that Virginia health plans provide coverage for effective treatment of all breast and lung cancer. Health plans cover radiation treatment, chemotherapy and brachytherapy for cancer treatment. VAHP indicated at the November 20, 2006 meeting that they wished to modify their earlier comments on Medicare coverage of IMRT. VAHP explained that both Medicare and Virginia health plan members can appeal adverse medical necessity decisions internally and externally with review by an independent physician panel.⁵⁹

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

IMRT is an alternative for traditional radiation treatment for some patients. The Mayo Foundation for Medical Education and Research stated that the 3-D CRT is a more standard radiation therapy that uses diagnostic imaging, computers and special software to conform the radiation beam to the shape of the tumor. The IMRT is the latest advance in 3-D CRT technology.⁶⁰

Mid-Rivers Cancer Center stated that IMRT for breast cancer serves as an alternative to mastectomy. IMRT reduces the toxicity of conventional radiation by improving dose homogeneity through an irregular object using true 3D modulation. They raised concern that reduced toxicity, such as burns means less time lost from work and improved cosmetic results. Mid-Rivers Cancer Center explained that by protecting the lung better through lower doses, it is suspected that the risk of lung problems would be reduced. This treatment can be quantified through lower doses, lower V20 (the volume of lung receiving a dose of 20Gy) and lower V5 in IMRT lung cancer patients compared with 3D patients.⁶¹

According to the JLARC report on the Evaluation of House Bill 1405, brachytherapy is another alternative to IMRT in some cases. The JLARC report stated:

Brachytherapy is a sealed source form of radiotherapy where a radioactive source is placed inside or next to the area requiring treatment. Experts indicate that brachytherapy is largely tumor stage dependent and limited to certain types of cancer. Therefore, it is not an alternative to IMRT as frequently as is 3D-CRT. The costs of brachytherapy could range significantly. However, an example provided by the Virginia Commonwealth University Massey Cancer Center based on 2006 Medicare rates shows the total cost of providing treatment with brachytherapy to be comparable to the cost of treatment with IMRT. Medical experts indicate that there may be situations where an alternative to IMRT does not exist. This could occur, for example, in a patient who has received prior radiation treatments and whose healthy tissue could not withstand further radiation exposure.⁶²

Trinity Health reported payments for a course of 37 conventional radiation oncology treatments at \$100 each (\$3,700) as compared to 37 IMRT treatments at \$400 each (\$14,800).⁶³

The *Neck Cancer Center Pained* article reported that IMRT is more expensive than 3-D conformal radiation treatments. The Mid-Rivers Cancer Center received approximately \$617 per treatment IMRT. The article reported that treatment for some breast cancer patients that include 26 IMRT sessions may cost approximately \$16,000 compared to \$82 per treatment for 3-D conformal treatments which would total \$2,100.⁶⁴

- 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.*

It is unlikely that the proposed mandate would significantly affect the number and types of providers in the next five years due to the expenses associated with equipment and training.

- 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.*

Five respondents to the Bureau of Insurance survey provided cost figures that ranged from less than \$.36 to \$15.58 per month per standard individual policyholder to provide coverage required by House Bill 1405. Twenty-one respondents reported cost figures that ranged from \$0.00 to \$13.81 per month per standard group certificate. Four insurers that estimated the cost of providing coverage on an optional basis provided cost figures of \$.90 to \$4.00 per month per individual policyholder. Fifteen insurers provided cost figures for coverage required by House Bill 1405 on an optional basis of \$0.00 to \$22.53 per month per group certificateholder.

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

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

The Mid-Rivers Cancer Center stated that it is anticipated that House Bill 1405 would maintain the total cost of radiation therapy. They explained that IMRT is an effective and safe treatment that reduces toxicity and long-term consequences of necessary cancer treatment. Mid-Rivers Cancer Center raised concern that reduced toxicity, such as burns means less time lost from work and improved cosmetic results.⁶⁵

MEDICAL EFFICACY

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

A proponent provided two abstracts relating to the efficacy of IMRT to the Advisory Commission. The first abstract was "Abstract Plenary 1: Phase III Randomized Study of Intensity Modulated Radiation Therapy Versus Standard Wedging Technique for Adjuvant Breast Radiotherapy." The objective of the

study was to evaluate if breast intensity modulated radiation therapy (BIMRT) translates into a reduction in acute skin toxicity compared to WC. The study included 331 patients in its analysis. The abstract reported that “BIMRT significantly improves dose distribution homogeneity and particularly the hot-spot to the breast crease.” The study concluded that “compared to the standard wedge compensation radiation treatment, BIMRT significantly reduces the development of severe moist desquamation.” The study recommended BIMRT for adjuvant radiotherapy of breast cancer.⁶⁶

The second abstract was “Abstract 1079: Intensity Modulation Radiation Therapy Results in a Significant Decrease in Clinical Toxicities When Compared to Conventional Wedge Based Radiation Therapy.” The objective of the study was to determine if IMRT results in a benefit in clinical outcomes. The study included 172 patients in the analysis. The study concluded:

Improved dose distribution with the use of IMRT in the treatment of whole breast results in a significant decrease in acute dermatitis, edema, and hyperpigmentation as well as a reduction in the development of chronic breast edema compared to conventional wedge based radiation treatment.⁶⁷

The 2003 Trinity Health report noted that one of the most important goals of IMRT includes sparing the normal tissue by reducing the toxicity to surrounding areas, this minimization of peripheral damage permits IMRT to improve cancer control and cure by delivering intensified doses to the targeted areas of tumor.⁶⁸

Radiation oncologists at the Mayo Clinic consider IMRT to be ideal for patients diagnosed with prostate cancer in addition to benign and malignant tumors of the head and neck, and other organs that lie near important body parts including the eyes, optic nerves, brain, brain stem, salivary glands, bladder, rectum, small bowel, kidneys, liver, lung and spinal cord.⁶⁹

A study by Claus and Associates (2001) examined the use of IMRT for the treatments of patients with ethmoid sinus tumors were included in the policy bulletin of one insurer. The study noted that IMRT has the potential to save binocular vision because the dose to the optic pathway structures can be reduced selectively by this process.⁷⁰

A representative of Anthem Blue Cross Blue Shield testified at the public hearing on October 17, 2006. In November 2005, Anthem developed a policy for coverage of IMRT. Prior to November 2005, there was no policy on IMRT. The Medical Director explained that two items caused Anthem to review the technology: (1) Medicare’s administrator, TrailBlazer changed their position on IMRT and (2) BCBS Technology Evaluation Committee’s report on IMRT therapy for breast and lung cancers. The report raised three points: (1) Clinical studies must test whether IMRT improves tumor control and reduces toxicity when compared to conventional 3D radiation therapy. The opponent reported that

there were no studies that directly compared the health outcomes between IMRT and conventional radiation therapy. (2) Anthem also performed its own independent research and reviewed research from Europe. It was determined that IMRT would be considered medically necessary for prostate, head and neck, and CNS lesions. It would be investigational for breast and lung cancer, and not medically necessary for brachytherapy. (3) The American Society for Therapeutic Radiology Oncology (ASTRO), a society for oncologists including radiation oncologists performed a phase three clinical trial for brachytherapy. Anthem reported that brachytherapy was successful for certain kinds of breast cancer. After reviewing that study, Anthem changed their position and started providing coverage for brachytherapy. Anthem's Medical Director clarified that prostate cancer was included on Anthem's original list of covered sites for IMRT and that Anthem was not sure if the coverage decision for breast cancer would be reversed. The Medical Director reported that Anthem had six external appeals for IMRT that were reviewed including: two for breast (one upheld), two for lung (one upheld), one for liver (upheld), and one for a spinal tumor. Anthem stated that as new technology becomes available, it raises the issue of safety and effectiveness. She stated that their technical assessment considers IMRT investigational for lung and breast cancer.⁷¹

Written comments from the VAHP raised concerns that while the risks are minimal for tumors of the prostate, head, and neck, they are very substantial for any tumors of the breast and lungs. They explained that IMRT is a direct beam of radiation honing in a specific area either to shrink an existing tumor or to eradicate cancer cells that could not be removed during surgery. It was stated that some companies noted that when a person breathes, the computer controlled laser does not factor in the movement of the chest cavity, putting the individual at risk in damaging healthy cells.⁷²

VAHP reported that there are no medical studies that support that IMRT is as effective as radiation procedures already covered. The NCI has affirmed "there are no published reports at present of prospective randomized clinical studies involving IMRT, and this lack of information clearly limits our knowledge of the effect of the use of IMRT on clinical outcomes." The VAHP stated that the Blue Cross Blue Shield Association Technology Evaluation on IMRT concluded that "available data are insufficient to determine whether IMRT is superior to 3D-CRT for improving health outcomes of patients."⁷³

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.*

Proponents believe that House Bill 1405 addresses both the medical and social needs of treating cancer patients with IMRT. The benefit is consistent with the role of health insurance.

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

The NCCN guidelines on prostate cancer identified IMRT as an alternative to 3-D conformal radiation therapy for ultra-high dose (dosage of 75 Gy or more) radiation treatment of prostate cancer. The guidelines state that IMRT is not routinely indicated in breast cancer and that evidence at that time was primarily limited to descriptive studies, evaluations of technical feasibility, and dosimetric planning studies. There was a scarcity of evidence from clinical outcome studies, and no clinical outcomes studies directly compared the effectiveness of IMRT to 3-D conformal radiation therapy for breast cancer.⁷⁴

JLARC stated that current research on the usage of IMRT treatment for breast and lung cancer is not decisive regarding clinical outcomes, despite the tremendous volume of study during recent years. JLARC stated:

Medical efficacy is typically assessed based on the outcomes of clinical research. However, most studies on IMRT use for breast and lung cancers have not been based on the outcome of clinical trials, but rather dosimetric studies or compilations of existing research. Dosimetric studies typically rely on either radiation dose plans developed for a sample of patients using both IMRT and conventional techniques, or IMRT dose plans compared to clinical data for patients previously treated with conventional techniques.⁷⁵

JLARC stated that in the short term, it appears that the need for IMRT treatment does not outweigh potential costs. According to their findings, cancer sites where IMRT is used for prostate cancer, head and neck cancer are covered by most insurance companies. JLARC explained as medical technology changes and research advances, a

specific treatment may become obsolete in the future. The report concluded that the proposed mandate may increase the cost of insurance and that a mandate does not appear necessary at this time.⁷⁶

Written comments from the VAHP stated that mandating specific technology sets a bad precedent. The VAHP provided an article entitled, "The Controversy Over High-Dose Chemotherapy with Autologous Bone Marrow Transplant For Breast Cancer (HDC-ABMT)" regarding breast cancer. The article explained the discrepancy between physicians' and patients' perceptions of HDC-ABMT and the clinical trial findings left HMOs and other insurers in a tough position. The article stated:

Principles of fair resource allocation suggest that if a particular intervention is expensive and unproven, a health plan should steadfastly decline to pay for it as a therapy, regardless of how vocally the affected patient group protests. Paying for patients to receive the intervention in a clinical trial, on the other hand, may be quite justifiable if the intervention and the standard treatment stand in a state of clinical equipoise. Providing coverage for a costly and toxic intervention such as HDC-ABMT when its efficacy is unproven has serious ramifications for patients, clinical researchers, and the health care budget.⁷⁷

The VCC reiterated its long-standing opposition to expanding mandated health benefits. They stated that the cost of mandated health benefits is a significant part of the health care equation. VCC stated that on June 12, 2006, JLARC reported that mandates can increase the cost of health care. VCC also stated that on October 19, 2006, the Virginia's Joint Commission on Health Care showed that the number of employers offering health insurance continues to decline due to costs and that rising healthcare costs increase the number of uninsured people. The VCC believed that additional mandated health benefits would only add to the costs of providing healthcare.⁷⁸

VAHP explained that mandated health insurance benefits will only apply to those residents in Virginia covered by 'fully insured' health plans. House Bill 1405 will only benefit 25% of Virginia's population consisting mainly of small businesses that continues to struggle in obtaining affordable health insurance coverage. VAHP noted that according to the Kaiser Family foundation's Employer Health Benefits 2006 Annual Survey, as of 2000, premiums for family coverage have increased by 59%. Between 2005 and 2006, premiums for employer-sponsored health insurance have increased by 7.7% compared to and more than the amount of overall inflation (3.5%) and wage gains (3.8%). VAHP concluded that as health care costs rise, small employers are the most vulnerable in terms of their ability to continue and afford health coverage.⁷⁹

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

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insured.

RECOMMENDATION

The Advisory Commission voted on November 20, 2006 to recommend against the enactment of House Bill 1405 (Yes-9, No-3).

CONCLUSION

The Advisory Commission believed that based upon the information presented, reimbursement for most IMRT treatments is available; if coverage is denied, patients have the opportunity to file appeals to their insurer or HMO and may also request an external appeals review in some instances. The members believed a mandate is not necessary at this time.

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