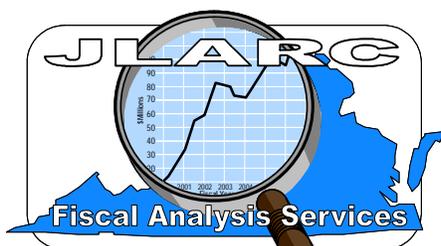


**JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY**

**EVALUATION OF PROPOSED
MANDATED HEALTH INSURANCE BENEFITS**

**Evaluation of House Bill 1405:
Mandated Coverage of
Intensity Modulated
Radiation Therapy (IMRT)
for Specified Cancer Sites**

October 2006



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JLARC provides evaluations of proposed health insurance mandates in accordance with Sections 2.2-2503 and 30-58.1 of the *Code of Virginia*.

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



Evaluation of House Bill 1405: Mandated Coverage of Intensity Modulated Radiation Therapy (IMRT) for Specified Cancer Sites

JLARC SUMMARY

Intensity Modulated Radiation Therapy (IMRT) is a significant advance in radiation technology which allows physicians to better target cancerous tumors while simultaneously sparing surrounding tissue. Recently, several third-party payers have limited their coverage of IMRT to specific cancer sites in the human body, which led to the proposal of HB 1405. Among the sites for which IMRT is no longer covered by some insurers are breast and lung cancer.

MEDICAL EFFICACY AND EFFECTIVENESS

There is a general consensus that sufficient medical evidence exists to support the use of IMRT for some cancer sites, in particular the prostate and head and neck. However, current medical evidence for the use of IMRT for other cancer sites, in particular breast and lung, is not as conclusive. Most existing research is based on dosimetric studies rather than clinical trials. These studies conclude that, while IMRT could lead to improved treatment and reduced morbidity in breast and lung cancer patients, further research demonstrating clinical outcomes is needed. However, medical experts at two Virginia medical schools assert that the current level of evidence is sufficient to demonstrate the superiority of IMRT over conventional techniques for breast cancer and lung cancer in some cases, particularly considering historical standards for the adoption of radiation technology.

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SOCIAL IMPACT

The availability of IMRT has increased significantly in recent years and may be offered at nearly all radiation treatment facilities across Virginia in the near future. However, the use of IMRT varies substantially among radiation therapy providers. IMRT is used most frequently to treat prostate cancer and head and neck cancer, but it is also used for other cancer sites including breast and lung cancers. Approximately one-third of health insurance companies appear to provide the level of coverage for IMRT mandated in HB 1405, although other insurers likely provide coverage for those sites where IMRT is used most frequently. For most patients without insurance coverage, treatment costs would be a significant expense.

FINANCIAL IMPACT

The proposed mandate would not have a significant impact on treatment costs, utilization, or most radiation providers in the near term because the cancer sites where IMRT is used most frequently are already generally covered by insurance. There may be an impact on radiation centers that use IMRT to frequently treat other types of cancer, such as breast and lung cancers. Based on survey responses from 21 insurance companies, the median monthly premium costs for the proposed mandate are estimated to range from \$1.00 to \$2.00, which appears to be within the range of the estimated impact of existing mandates. HB 1405 would increase the total cost of health care, but it would also increase the availability of IMRT, which may be particularly important for patients where it appears to be the only treatment option.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Whether the need for the proposed mandate outweighs the costs may be different in the short term than the long term. In the short term, the need does not appear to outweigh the costs because most insurance companies already provide coverage for the cancer sites where IMRT is used most frequently and its use is most widely accepted. However, medical experts indicate that future research may provide more conclusive evidence that IMRT is superior for cancer sites where it is now considered investigational by some insurance companies, including breast and lung cancers. In the absence of the mandate and if insurance companies do not modify their policies to reflect emerging research, the adoption of IMRT for other cancer sites may be impeded. An additional consideration is whether it is appropriate for the State to mandate a treatment as specific as IMRT. Medical technology and research will advance, which may make such a specific mandate obsolete in the future.



Evaluation of House Bill 1405: Mandated Coverage of Intensity Modulated Radiation Therapy (IMRT) for Specified Cancer Sites

House Bill 1405 of the 2006 General Assembly Session would require health insurance plans to provide coverage for treatment by intensity modulated radiation therapy (IMRT) for tumors in situations for which an extremely high level of precision is required to spare surrounding tissue. House Bill 1405 further specifies that IMRT shall be covered for 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, and pituitary tumors. House Bill 1405 also specifically includes compensator-based IMRT, which is a different approach from how IMRT is most frequently delivered. As with other health insurance mandates, this mandate does not apply to short-term travel, accident-only, or other types of limited policies, or federal plans, such as Medicare.

BACKGROUND

IMRT is a significant advance in radiation technology. Recently, several third-party payers have limited their coverage of IMRT to specific cancer sites, which led to the proposal of HB 1405. Of particular concern are policy changes that would no longer cover treatment with IMRT for breast or lung cancer. Because the concerns which led to this proposed mandate are primarily focused on coverage of IMRT for breast and lung cancers, this review will largely focus on these cancer sites.

a. Description of Medical Condition and Proposed Treatment

Medical experts consider IMRT to be one of the most significant advances in the field of radiation technology in the past ten years. Radiation is a common cancer therapy used to destroy cancer cells or prevent cancer cells from growing or reproducing. In so doing, it may provide a cure for cancer, control the disease, or help relieve its symptoms.

The evolution of radiation therapy technology has been based on the premise that improved targeting enables the delivery of higher

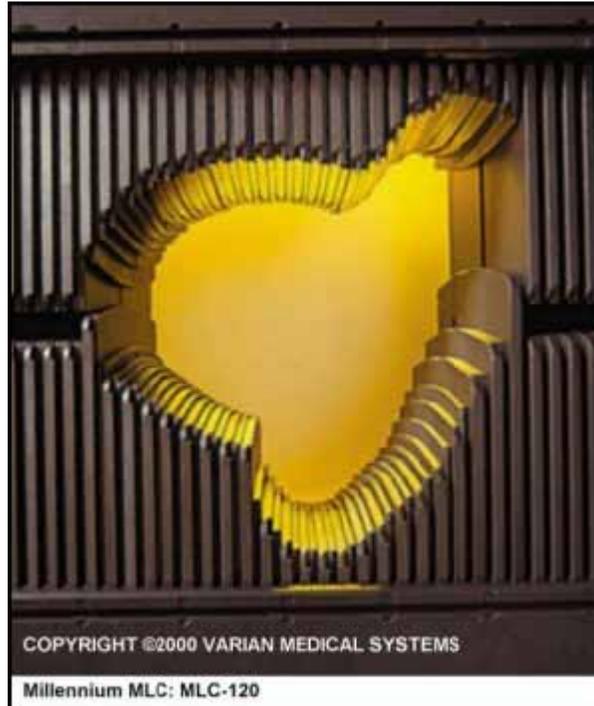
doses of radiation to cancerous tissue while simultaneously sparing normal tissue. IMRT is a significant advance in radiation technology in this regard. The ability to spare surrounding tissues is particularly important for tumors that are in close proximity to vital organs. Examples include prostate cancer, where the bladder and rectum are in close proximity, or cancers of the head and neck, where salivary glands, optic nerves, and other critical structures are of concern. Improved targeting also helps treat cancers in which tumors are wrapped around internal organs, such as the spinal cord, that are often irregularly shaped.

IMRT uses different approaches than conventional techniques to both the delivery and planning of radiation therapy. These differences allow for higher doses of radiation to the tumor while delivering less radiation to normal tissues. The precursor to IMRT is three-dimensional conformal radiation technology (3D-CRT). Both IMRT and 3D-CRT require a linear accelerator. However, with 3D-CRT radiation oncologists use 3D images and devices referred to as compensators, blocks, or wedges to manually shape the radiation beams to conform to the patient's tumor. 3D-CRT delivers radiation beams with a constant volume from two or three different directions. Computer algorithms are used to develop the dose volume for each beam, although dosimetrists may need to recalculate dose distributions to account for underdosing of the tumor or overdosing of nearby normal tissue.

IMRT is delivered through a computerized treatment and planning system that is better able to conform the radiation dose to the contour of the tumor and modulate the intensity of the radiation to protect surrounding tissue and account for inhomogeneities in the tumor. IMRT is typically delivered through a multi-leaf collimator (MLC), a device that is situated between the beam source and the patient and moves around the patient in an arc (Figure 1). As the MLC moves, a computer varies the aperture size independently and continuously for each leaf through which the radiation beam is delivered. Thus, MLCs are able to divide beams into thousands of narrow "beamlets," with intensities that range from zero to 100 percent. In contrast to conventional treatment with MLCs in which the collimator leaves remain static, IMRT allows the leaves to move during each therapy session.

Another advance of IMRT is the approach used for planning the patient's treatment. Prior generations of radiation therapy, such as 3D-CRT, rely on forward treatment planning which involves estimating the radiation delivery profile based on the number, directions, and shape of the radiation beams. As mentioned previously, forward treatment planning may require dosimetrists to make adjustments after the course of treatment has begun to adjust for is-

Figure 1: A Multileaf Collimator, Used for Delivering IMRT



Source: SMARTBEAM IMRT: Patient Information and Frequently Asked Questions; Varian Medical Systems

sues such as overdosing of healthy tissue or underdosing of the tumor. In contrast, IMRT typically relies on inverse treatment planning. With inverse planning, a radiation oncologist and medical physicist determine the treatment target, normal structures to be protected, required radiation dose for the tumor, and tolerated doses for the surrounding normal tissues. The computer then calculates the beam profiles needed to yield those results, which results in fewer problems related to unintended overdosage or underdosage of tissue.

Compensator-based IMRT is used less frequently than collimator-based IMRT and varies by using a fixed device to modulate the radiation beam. With compensator-based IMRT, a pre-shaped piece of material (the compensator) modulates the beam. The amount of modulation of the beam is based on the thickness of the material through which the beam is attenuated. Compensator-based IMRT requires the fabrication and manual insertion of the compensator into the linear accelerator which delivers the beam. While compensator-based IMRT is able to achieve some of the same effects as MLC-based IMRT, modulation of the radiation beam is done manually with compensator-based IMRT while these adjustments are made automatically with the MLC-based version. JLARC staff

are only aware of one provider in the State that currently makes use of compensator-based IMRT.

IMRT has been a significant advance and is an extremely powerful tool for delivering radiation therapy. It is also a relatively expensive technology, with a new machine costing about \$2 million. Due to the comparatively high dosage levels that can be delivered and the complex treatment planning involved, IMRT requires significant quality assurance measures and a highly specialized medical team (including a radiation oncologist, medical physicist, dosimetrist, radiation therapist, and radiation therapy nurse) to ensure that it is carried out safely. Further, as with other types of radiation therapy, receiving treatment with IMRT is an intensive and involved process for the patient.

b. History of Proposed Mandate

House Bill 1405 was introduced as a result of several providers' dissatisfaction with recent changes in the coverage policies for IMRT of two major third-party payers in Virginia—Medicare and Anthem Blue Cross and Blue Shield. In November 2005, the Medicare regional intermediary for Virginia, TrailBlazer Health Enterprises, announced a local coverage decision that Medicare would not cover the routine use of IMRT for breast cancer, colon cancer, and metastatic cancers to the vertebral bodies. (However, IMRT may be considered reasonable and necessary for these cancer sites when certain conditions exist.) Medicare's policy became effective on January 1, 2006.

In April 2006, Anthem implemented new coverage guidelines which indicate that IMRT is considered medically necessary in patients with non-metastatic prostate cancer, head and neck cancer, or central nervous system lesions with close proximity to the optic nerve or brain stem. Anthem's new guidelines further indicate that IMRT is considered investigational and not medically necessary in patients with all other types of cancer, including lung cancer, breast cancer, abdominal cancers, and cancers of unknown primary origin.

Both TrailBlazer and Anthem have indicated that they did not modify their coverage policies for IMRT but rather established coverage policies for this technology where no specific policy had existed previously. The policies of these third-party payers are particularly significant because many insurance companies follow Medicare's lead in setting their own coverage policies, and Anthem is one the largest private health insurers in Virginia.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of HB 1405 will have the opportunity to publicly express their views on the proposed mandate at the October 17, 2006, public hearing before the Special Advisory Commission on Mandated Health Insurance Benefits. Proponents of HB 1405 include certain providers of IMRT, particularly those who make frequent use of IMRT for breast and lung cancers, as well as patients receiving IMRT treatments. Opponents of IMRT include health insurance companies that have established coverage guidelines for IMRT that are more restrictive than would be required by HB 1405.

MEDICAL EFFICACY AND EFFECTIVENESS

There is a general consensus that sufficient medical evidence exists to support the use of IMRT for certain cancer sites, such as the prostate and the head and neck, and these cancer sites appear to be covered by most insurance companies. However, the medical evidence for the use of IMRT for other cancer sites is not as conclusive. Because the current proposed mandate is largely related to recent changes in insurance coverage for breast and lung cancers, this review focuses primarily on these two cancer sites. Most existing research concludes that, while IMRT could lead to improved treatment and reduced morbidity in breast and lung cancer patients, further research demonstrating clinical outcomes is needed. However, medical experts at Virginia's medical schools assert that the current level of evidence in the medical literature is sufficient to demonstrate the superiority of IMRT over conventional techniques, including for breast and lung cancers, particularly considering historical standards for the adoption of radiation technology.

a. Medical Efficacy of Treatment

The current research on the use of IMRT for breast and lung cancers is not conclusive with respect to clinical outcomes, despite a large volume of research published in recent years. (Specific research examined for this review is listed in Appendix D.) 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. In either case, the dose plans and expected outcomes are compared, not actual clinical outcomes.

Medical Efficacy

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

Breast and lung cancers have unique characteristics that present additional challenges for the use of IMRT which may not be reflected in dosimetric studies. Most notably, while cancers of the prostate and head and neck are relatively stationary, organ motion resulting from respiration and cardiac pulsation can be significant with breast and lung cancers. For example, the motion of a lung tumor as a result of respiration can be as much as several centimeters. In addition, lung tumors are surrounded by highly radiosensitive and low-density lung tissue. Due to the high dose volumes and conformal nature of IMRT, there is concern that there may be greater risk with breast and lung cancers of underdosing tumors or overdosing healthy critical structures. These concerns may not be reflected in dose studies which are based on static treatment plans. Thus, while most recent studies have concluded that IMRT could lead to improved treatment and reduced morbidity in breast and lung cancer patients over conventional radiation therapies, these studies often also indicate that further research demonstrating clinical outcomes are needed before firm conclusions can be drawn. Although there have not yet been any published studies of randomized clinical trials for breast or lung cancer patients, forthcoming research results in a recent Canadian study may address this concern.

b. Medical Effectiveness of Treatment

Medical Effectiveness

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

As discussed previously, there have been few published studies outside of dosimetric studies or summaries of existing research that compare IMRT to conventional treatments for breast and lung cancers. However, radiation oncology practice guidelines for IMRT are relevant, as is the medical expertise of practicing radiation oncologists who are familiar with the field as a whole and with the evolution of radiation oncology as a treatment modality.

The National Cancer Institute (NCI), the American College of Radiology (ACR), and the American Society for Therapeutic Radiology and Oncology (ASTRO) have all developed guidelines for IMRT. However, as with other forms of radiation technology, these guidelines largely address the planning and delivery of IMRT and do not specify which treatment sites IMRT is indicated for.

NCI has not addressed the use of IMRT for specific cancer sites, but current guidelines for the use of IMRT in clinical trials state the following:

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.

ASTRO and ACR's joint 2005 radiation oncology coding guidelines list the common clinical indications for IMRT and address medical necessity for the treatment. According to the ASTRO/ACR guidelines, the most common sites that currently support the use of IMRT include primary tumors of the central nervous system, metastatic tumors of the central nervous system, primary or metastatic lesions to the head and neck, carcinoma of the prostate, and other pelvic and retroperitoneal tumors. However, the guidelines also state that other sites that meet the criteria for "medical necessity" should be considered appropriate and that medical necessity is "not limited by specific diagnosis as much as by clinical circumstance." The guidelines specify that IMRT is clinically indicated when highly conformal dose planning is required and provide specific conditions pertaining to medical necessity. Thus, it appears that according to ASTRO/ACR guidelines, the use of IMRT for breast and lung cancers may be appropriate in at least some circumstances. ACR has also released a sample letter for IMRT providers to use in response to non-coverage by private payers which lists lung cancer among those sites where IMRT is medically necessary:

The ACR supports the application of IMRT as a medically necessary, non-investigational procedure that is indicated for primary brain tumors, brain metastasis, prostate cancer, lung cancer, spinal cord tumors, head and neck cancer, pituitary tumors and situations in which extremely high precision is required.

Experts at two Virginia medical schools independently agreed that medical evidence supports the use of IMRT for breast and lung cancers in cases where it is medically warranted. They contend that existing medical research demonstrates clear-cut dosimetric advantages to IMRT for both breast and lung cancer, and they indicate that the primary issue is not the tumor site but the healthy tissue that needs to be protected. There is strong evidence on the benefits of reducing normal tissue exposure at other sites that can be extrapolated to breast and lung cancers, as well as research on the dose volume that can be tolerated at these sites generally. Experts also point out that as radiotherapy has evolved, the introduction of new technologies has not been accompanied by studies systematically demonstrating their superiority over predecessors. Such trials are difficult because they would require large numbers of patients due to patient heterogeneity, and it has generally been

the position of the radiation oncology community that the benefits of improved dose targeting were self-evident.

For these reasons, experts assert that the level of documentation currently in the literature demonstrating the superiority of IMRT, including its use for breast and lung cancers, is sufficient. Furthermore, experts contend that the decision of whether IMRT is the best technology in a particular situation should be left to the treating physicians.

SOCIAL IMPACT

The use of IMRT appears to have increased significantly in recent years. However, IMRT utilization varies substantially across radiation therapy providers. IMRT is used most frequently to treat prostate cancer and head and neck cancers, but it is also used for a variety of other cancer sites including breast and lung. Based on a survey of health insurance companies conducted by the Bureau of Insurance, approximately one-third of health insurance companies already provide the level of coverage for IMRT required by HB 1405. Other companies likely provide some coverage for IMRT, most likely for those cancer sites where the medical evidence is most conclusive, but not to the extent that would be required by the proposed mandate. For patients without health insurance coverage, out-of-pocket costs for IMRT are estimated to be \$16,500 or more and would constitute over one-third of median household income in Virginia. Thus, it appears that IMRT treatment is likely to be a significant expense for most individuals without insurance coverage.

a. Utilization of Treatment

IMRT is a relatively new type of radiation therapy, and its utilization appears to have increased significantly in the last few years. It is used most frequently to treat prostate cancer and cancer of the head and neck, although utilization rates appear to vary across providers. Recent changes in IMRT coverage by insurers may affect IMRT utilization for some cancer sites. These changes will not affect the sites that IMRT is currently used for most frequently. However, they could affect the rate at which IMRT is adopted for other sites in the future.

Accurate data on the rates of IMRT use are not available at the State or national level. Although the Virginia Cancer Registry collects data at the State level, there appears to be a problem with underreporting by providers. Data on the rates of IMRT use do not appear to be collected at the national level.

Although aggregate utilization rates for IMRT are unavailable, recent research on the number of radiation providers who use IMRT indicates a significant increase in utilization of this treatment. Based on research published in the September 2005 issue of *Cancer*, the proportion of radiation oncologists nationally who use IMRT has increased from an estimated 32 percent in 2002 to an estimated 73 percent in 2004. According to the article, these estimates are based on a random sample of radiation oncologists across the United States.

IMRT is used most frequently to treat genitourinary cancers, such as prostate cancer, and cancers of the head and neck. Based on those radiation oncologists in the national sample who provided IMRT, 85 percent of physicians reported treating genitourinary cancers with IMRT, and 81 percent reported treating head and neck cancer with the therapy. Cancer of the central nervous system was the third most frequently reported site with 67 percent of physicians using IMRT for this purpose. Seven other cancer sites were reported where at least ten percent of oncologists surveyed used IMRT, including breast cancer (26 percent of respondents) and lung cancer (18 percent of respondents).

While data on the rates of utilization of IMRT are unavailable at an aggregate level, it appears utilization rates vary considerably. Of those radiation oncologists in the national survey who used IMRT, 73 percent reported treating less than 25 percent of patients with IMRT. However, select sources in Virginia that provided utilization rates of IMRT compared to other radiation alternatives show how rates can vary by provider and cancer site. Utilization rates for IMRT, 3D-CRT, and brachytherapy were provided by the Virginia Commonwealth University Massey Cancer Center, the University of Virginia (UVA) Health System, and the State employee health plan. (Brachytherapy is described below under the "Serves as an Alternative" criterion, page 18.) These rates were provided for prostate cancer, head and neck cancer, breast cancer, and lung cancer.

Table 1 shows the utilization of IMRT, 3D-CRT, and brachytherapy by two State university health systems. (These utilization rates largely reflect patient volume prior to the recent changes in Medicare and Anthem coverage.) Both systems show comparatively high utilization rates for prostate cancer and head and neck cancer. VCU also reports a comparable IMRT utilization rate for breast cancer. However, there is a significant variance in the frequency with which the two systems provide IMRT compared to alternative therapies. With the exception of head and neck cancer, radiation patients at the VCU Massey Cancer Center received IMRT much more frequently than patients treated through the UVA Health System.

Medical experts at these two universities indicate that variances in utilization reflect differences in capacity resulting from how medical centers have invested limited financial resources, and the fact that IMRT is still an emerging technology. UVA medical staff indicated that they expect utilization rates for IMRT to increase at UVA in the near future with the acquisition of new technology. VCU medical staff also indicate that VCU has been a pioneer in the technology for the assessment and compensation of tumor movement when breathing, which may also help explain its higher IMRT utilization rates for breast and lung cancer.

Table 1: Utilization of IMRT and Alternative Radiation Therapies at the VCU Massey Cancer Center and the UVA Health System, FY 2006

Cancer Sites	% of Patients in the VCU Massey Cancer Center*	% of Patients in the UVA Health System
Prostate Cancer		
IMRT	49%	16%
3D-CRT	46%	17%
Brachytherapy & other radiation therapies	5%	65%
Head & Neck Cancer		
IMRT	47%	65%
3D-CRT	54%	35%
Brachytherapy & other radiation therapies	0%	--
Breast Cancer		
IMRT	49%	2%
3D-CRT	39%	98%
Brachytherapy & other radiation therapies	12%	--
Lung Cancer		
IMRT	28%	5%
3D-CRT	61%	95%
Brachytherapy & other radiation therapies	11%	--

Note: Site groupings are for malignant neoplasms. Percentages may not add to 100 percent because patients may have been treated with more than one type of therapy.

*Data from VCU Health System hospital billing claims as of 6/30/2006. Treatment type was determined by CPT codes for treatments delivered during FY 2006. Cancer site groupings were determined by the primary diagnosis on the account.

Source: Virginia Commonwealth University Massey Cancer Center and the University of Virginia Health System, 2006.

Table 2 shows the proportion of members in the State health plan receiving IMRT, 3D-CRT, and brachytherapy over a 30-month period from January 1, 2004, through June 30, 2006. These individuals received therapy from a variety of providers. Compared to the university health systems, a much smaller proportion of patients received IMRT treatment across all four cancer sites. However, it is important to note that the data in Table 2 is aggregated across 2 1/2 years, and utilization of IMRT may have changed during this time span. Also, some members of the State health plan may have received treatment at radiation centers that did not provide IMRT, and these data may reflect differences in radiation treatment practices at centers outside the university health systems.

Several factors may change future utilization of IMRT. As radiation technology advances and more providers adopt IMRT, the utilization of this technology is likely to increase. This is particularly true for prostate and head and neck cancers, and other sites where there is a consensus that IMRT is the most appropriate treatment. In contrast, reduced insurance coverage for IMRT for other cancer sites, such as breast and lung cancers, will likely cause utilization to drop for these sites. However, Tables 1 and 2 show that, with the exception of VCU, which appears to be a relatively high user of IMRT, among at least a subset of Virginia providers IMRT was used for only very select breast and lung cancer patients, even prior to recent changes in insurance coverage. Still,

Table 2: Utilization of IMRT and Alternative Radiation Therapies for State Health Plan Members (January 1, 2004—June 30, 2006)

	% of Members Receiving Treatment
Prostate Cancer	
IMRT	12%
3D-CRT	57%
Brachytherapy	31%
Head and Neck Cancer	
IMRT	13%
3D-CRT	83%
Brachytherapy	4%
Breast Cancer	
IMRT	0%
3D-CRT	96%
Brachytherapy	4%
Lung Cancer	
IMRT	0%
3D-CRT	99%
Brachytherapy	1%

Source: Anthem Blue Cross and Blue Shield.

there is concern among some medical experts that if existing coverage policies remain in effect, this may impede the adoption of IMRT for certain cancer sites, even if forthcoming clinical research studies provide more conclusive evidence of their medical efficacy.

b. Availability of Coverage

Approximately one-third of health insurers providing fully insured plans to which the mandate would apply appear to provide the level of coverage for IMRT proposed by HB 1405 based on a survey of 50 health insurance providers conducted by the Bureau of Insurance (BOI) (Table 3). Ten companies responded that they provide the full level of coverage proposed by the mandate. Another 21 companies responded that they provide a subset of the IMRT coverage mandated by HB 1405. These companies indicated that either they do not provide coverage for specified cancer sites in the mandate or they do not provide coverage when IMRT is considered experimental or investigational. (Some cancer sites covered by the mandate, such as breast cancer and lung cancer, are considered experimental or investigational by some insurance companies.) Another four companies responded that they do not provide the level of IMRT coverage required by HB 1405, although most probably provide at least some level of coverage for IMRT. Eight insurance companies responding to the BOI survey indicated that HB 1405 would not apply to their insurance plans for reasons such as they no longer issue health insurance.

Table 3: Levels of Health Insurance Coverage Provided for IMRT

Coverage Status in Relation to Coverage Proposed by HB 1405	# of Insurers
Provides Full Coverage	10
Provides a Subset of Coverage	21
Does Not Provide Coverage in Proposed Mandate	4
Mandate Does not Apply	8
Total Companies Responding	43

Source: Virginia Bureau of Insurance survey of 50 health insurance companies, 2006.

c. Availability of Treatment

Data are not currently available to indicate where IMRT is offered in Virginia. A linear accelerator is required to deliver IMRT, and the Virginia Department of Health (VDH) registers and inspects all operational linear accelerators in Virginia. However, not all linear accelerators are capable of delivering IMRT, and VDH's database does not differentiate between which linear accelerators have this capability. As of July 31, 2006, VDH reported 45 facilities with linear accelerators in Virginia. Radiation facilities with linear ac-

celerators are located in each of the five health planning regions in Virginia, and each planning region has at least six or more facilities with a linear accelerator.

Although there is not conclusive data to indicate which radiation facilities in Virginia offer IMRT, it is likely that most radiation facilities with a linear accelerator currently provide IMRT or will begin doing so in the near future. As mentioned previously, a random sample of radiation oncologists across the United States indicated a significant increase in the adoption of IMRT in recent years with 73 percent of radiation oncologists reporting using IMRT in 2004. Further, 91 percent of nonusers in the sample planned to adopt IMRT in the future, with nearly 60 percent planning to adopt it within the next year.

d. Availability of Treatment Without Coverage

As discussed in the next section, the cost of IMRT is sufficiently high that some individuals are unlikely to seek this form of radiation treatment without health insurance coverage. Patients whose health insurance policies do not cover IMRT for their cancer site would most likely receive conventional 3D-CRT treatment, which is more widely covered by health insurance. In some cases, a patient may also receive brachytherapy (discussed further under "Serves as an Alternative," page 18).

e. Financial Hardship

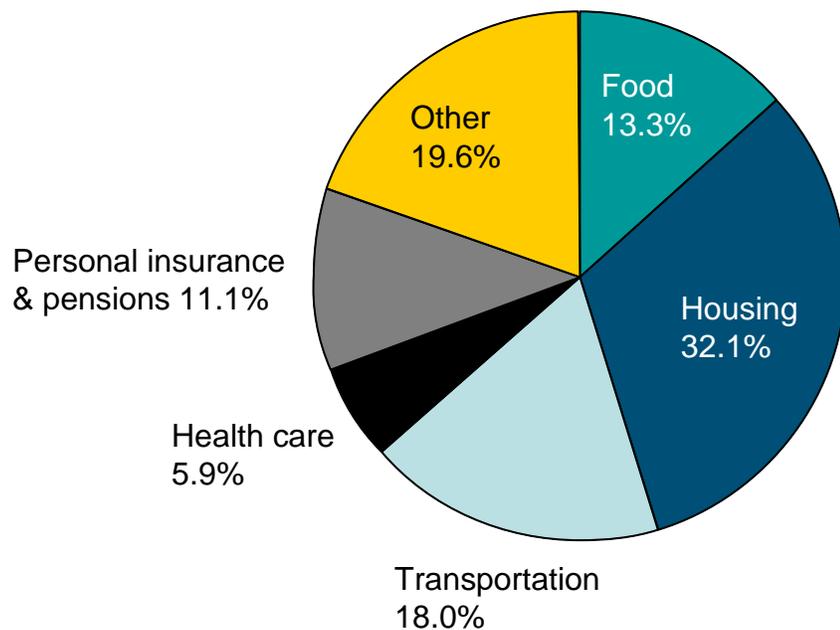
The cost of obtaining treatment with IMRT could result in considerable financial hardship for some individuals lacking health insurance coverage. Treatment costs for each individual will vary depending on a variety of factors, including the type of cancer, the complexity of the treatment planning, and the total number of treatments a patient receives. An example provided by the Massey Cancer Center indicates that a typical course of treatment with IMRT for a moderate complexity tumor could cost approximately \$16,500, based on 2006 Medicare reimbursement rates. This estimate includes both the direct cost of delivering the treatment (approximately 60 percent of the total cost) and related costs that would be incurred by the patient, such as physician consultations and treatment planning costs. Medicare rates are probably significantly below the reimbursement amounts paid by private insurance companies, and even further below hospital and physician charges. However, Medicare rates provide a baseline for the potential magnitude of costs for IMRT treatment.

The estimated 2006 median household income in Virginia is \$56,575 based on data from the U.S. Census Bureau and adjusted for inflation. The estimated IMRT treatment cost (\$16,500), there-

fore, would consume nearly 30 percent of median household income. Because \$16,500 is likely a conservative estimate of treatment cost, actual treatment costs could be well over a third of household income. This also does not take into consideration other costs associated with treatment, such as extended stays of patients and family in areas away from home and work.

Figure 2 shows the average distribution of total annual expenditures by major category based on the Bureau of Labor Statistics annual Consumer Expenditure Survey. As shown in Figure 2, on average the largest share of expenditures (32.1 percent) is for housing. Health care makes up 5.9 percent of expenditures on average. Therefore, payment of IMRT treatment out of pocket would result in over a five-fold increase in the proportion of expenditures typically dedicated to health care. It would also put the magnitude of health-care expenditures on par with housing costs.

Figure 2: Distribution of Total Annual Household Expenditures by Major Category, 2004



Source: Bureau of Labor Statistics, Consumer Expenditure Survey, 2004.

f. Prevalence/Incidence of Condition

Incidence rates for the cancer sites included in this review are shown on Table 4. Prostate cancer is the most frequently occurring cancer based on its incidence in men followed by female breast cancer. Table 4 shows incidence rates based on actual incidence data reported to the Virginia Cancer Registry. Based on incidence rates estimated by the American Cancer Society (ACS), it appears that cancer registry rates may be underreported slightly, but only by around five percent. For 2006, ACS estimates on new cancer cases in Virginia include: 6,000 for prostate, 6,080 for female breast, and 4,840 for lung.

Estimates of the incidence of cancers are not indicative of the demand for IMRT treatment. IMRT is not always the best treatment option and is currently only used to treat a subset of individuals with the cancers listed in Table 4. Further, utilization rates among providers vary considerably, so it is not possible to extrapolate the utilization rates of a few providers to estimate the demand for treatment statewide.

Table 4: 2003 Cancer Incidence Rates in Virginia by Cancer Site (Rates per 100,000 Age-Adjusted to 2000 U.S. Standard Population)

Cancer Site	2003 Reported Incidence Rate*
Prostate	154.5
Female Breast	117.1
Lung	69.2
Head & Neck	10.8

*Sex-specific cancer rates are calculated using population values that are appropriate.

Source: Virginia Cancer Registry, 2006.

g. Demand for Coverage

As of October 10, 2006, three physicians in Virginia, four physicians from other states, one medical physicist in Maryland, and one dosimetrist in North Carolina have formally indicated support for HB 1405. However, given that a quarter of insurance companies already appear to offer the level of coverage in the proposed mandate and many more offer the benefit on a more limited basis, actual demand is likely higher. At least some other providers of IMRT would probably support the bill, particularly those that treat a comparatively high volume of breast and lung cancer patients with IMRT. In addition, breast and lung cancer patients whose treating physician feel that IMRT is the best treatment alternative would probably support the bill. However, it is difficult to extrapo-

late patient support based on the estimated number of new breast and lung cancer patients because IMRT utilization rates vary widely among radiation therapy providers. Interested parties will have the opportunity to formally voice their support for HB 1405 at the October 17, 2006, public hearing before the Special Advisory Commission on Mandated Health Insurance Benefits.

h. Labor Union Coverage

Labor unions do not appear to have advocated specifically for the inclusion of IMRT coverage in their health benefit packages. Union representatives contacted indicated that unions typically advocate for broader health benefits, rather than benefits as specific as the cancer sites where IMRT is covered.

i. State Agency Findings

There have been no State agency findings or reports addressing the issues covered in this evaluation as they relate specifically to IMRT. However, VDH provided data on the incidence rates of cancers addressed in this evaluation. Also, in 1999 the Special Advisory Commission considered a bill that would have revised the *Code of Virginia* provision (Section 35.2-3407.5) prohibiting the denial of coverage of certain Food and Drug Administration (FDA) approved prescription drugs for the treatment of cancer if they have not been FDA approved for the specific type of cancer for which the drug is being prescribed. The proposed bill would have amended the *Code* to include not only prescription drugs but also "surgical procedure, radiation, other therapy or supportive care prescribed for the treatment of cancer." The Advisory Commission voted to recommend against the enactment of the bill, but recommended that health insurance policies be precluded from denying coverage for a specific drug, therapy, or procedure prescribed for cancer treatment solely on the grounds that it is not FDA-approved for that particular type of cancer.

j. Public Payer Coverage

Medicaid and Medicare provide coverage of IMRT, although at differing levels. Medicaid does not have a written policy on IMRT, but according to Department of Medical Assistance Services (DMAS) staff, Medicaid covers IMRT in all cases where it is medically justified. Therefore, Medicaid provides coverage for IMRT that is comparable to the level included in the proposed mandate. In particular, Medicaid covers IMRT for both breast and lung cancer.

Medicare's coverage policy for IMRT is more limited. As mentioned previously, as of January 1, 2006, Medicare in Virginia does not

cover the routine use of IMRT for several indications including breast cancer, colon cancer, and metastatic cancers to the vertebral bodies. However, Medicare acknowledges that IMRT still may be considered reasonable and necessary for these sites (with supporting medical documentation) when at least one of several justifying conditions exist. These conditions include vital structures that are in close proximity to the tumor, tumor volume that has been previously irradiated, gross tumor volume margins that are irregular, and situations in which only IMRT would decrease the probability of grade 2 or grade 3 radiation toxicity.

k. Public Health Impact

Public Health

The role of public health is to protect and improve the health of a community through preventive medicine, health education, and control of communicable diseases.

The proposed mandate would potentially benefit those individuals receiving IMRT treatment for cancer sites that may not otherwise be covered, as well as those radiation centers providing the treatment. There is not a significant public health impact associated with this bill at this time. However, there are potential future public health issues that should be considered. In the absence of the mandate, there is the risk of hindering the adoption of IMRT for additional cancer sites, even if forthcoming research shows positive clinical results. This may be particularly the case if conventional techniques are covered by insurance and insurers are slow to update their policies. Conversely, adoption of the proposed mandate risks mandating coverage of a treatment for certain cancer sites for which research has not provided definitive clinical results. There is at least one example of a current Virginia mandate where it was later determined that the treatment covered by the mandate was not appropriate in some cases.

FINANCIAL IMPACT

The proposed mandate would not have a significant impact on IMRT treatment costs, IMRT utilization, or most radiation providers in the near term because the cancer sites where IMRT is used most frequently, such as prostate cancer and head and neck cancer, already appear to be covered by most insurance companies. However, the proposed mandate may impact radiation centers that use IMRT to treat a substantial portion of patients with other types of cancer, in particular breast and lung cancers. It would also increase the availability of IMRT for patients, particularly in those cases where it is determined to be medically necessary or is the only treatment option, and it may reduce negative side effects that result from the more conventional treatments. Because IMRT is more expensive than conventional treatments, it would also increase the cost of health care, at least in the short term, and is estimated to result in median monthly premium increases ranging from \$1.00 to \$2.00.

a. Effect on Cost of Treatment

The proposed mandate would likely have a minimal effect on the cost of providing IMRT. It appears most health insurance companies already cover IMRT for those cancer sites where it is used most frequently—prostate cancer and head and neck cancer. For these situations, the mandate would not have an effect on costs.

It is possible that recent insurance coverage limitations on breast and lung cancers may result in some providers who previously used IMRT for these cancer sites attempting to renegotiate higher reimbursement rates for remaining patients to offset lost revenue. The proposed mandate could mitigate this effect, which is more an issue of reimbursement than of cost. However, insurance companies indicate that, in most cases, IMRT is just one of many treatments administered by a provider and that reimbursement rates are typically not negotiated at this level of detail.

b. Change in Utilization

Utilization of IMRT for those cancer sites where it is used most frequently, in particular prostate cancer and head and neck cancer, would not be affected by the mandate because it appears that most health insurance companies already provide coverage for these cancer sites. Utilization of IMRT for other cancer sites where health insurance coverage is not as widespread, such as breast cancer and lung cancer, would be affected. However, the mandate's impact would depend on how frequently radiation oncologists use IMRT for these cancer sites.

As indicated previously, there appears to be a substantial range in the utilization of IMRT at different treatment centers. At UVA, IMRT is used to treat a relatively small fraction of breast and lung cancer patients. When asked whether UVA would experience a significant reduction in the use of IMRT as a result of the recent insurance coverage decisions, UVA Health System staff reported that it would not: "At most we will have a moderate reduction because we have used IMRT for highly selected cases of breast and lung cancer." In this case, it appears the mandate would have little effect on utilization rates.

In contrast, it would appear that the impact of the mandate would be higher at VCU's Massey Cancer Center where a much larger share of breast and lung cancer patients are treated with IMRT. For example, VCU indicated that as a result of the recent changes in Medicare coverage, 55 percent of Medicare cases that were previously treated with IMRT would now be treated with alternative means of radiation therapy or not at all. VCU further stated that 72 percent of Anthem cases treated with IMRT in FY 2005 would

have been affected by Anthem's recent change in coverage. For providers such as VCU that use IMRT more frequently for breast and lung cancer patients, the mandate would have more significant impact.

c. Serves as an Alternative

The main alternative to IMRT is three-dimensional conformal radiation technology (3D-CRT). Medical experts indicate that, in most cases, 3D-CRT would be used if IMRT were unavailable, although potentially with less successful results and more negative health side effects. A more detailed discussion of the treatment differences between IMRT and 3D-CRT technology is provided in the background section of this evaluation. However, in addition to differences in treatment, there are significant differences in cost between the two technologies. Based on 2006 Medicare rates, IMRT is approximately 2.5 times more expensive than 3D-CRT for the delivery of radiation treatment. An illustrative cost model prepared by the VCU Massey Cancer Center including all related costs (direct and indirect) of providing 3D-CRT shows IMRT to be about twice as expensive as 3D-CRT in total costs.

Brachytherapy is another alternative to IMRT in some cases. In contrast to IMRT and 3D-CRT, which are external beam radiotherapy techniques, 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 cancers. 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 VCU 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.

d. Effect on Providers

In general, it appears that the proposed mandate would not have a significant impact on the number of existing IMRT providers in Virginia. While the rate of adoption of IMRT has increased substantially in recent years, IMRT appears to be used with a limited number of cancer patients. A 2004 survey of radiation oncologists across the United States indicated that 73 percent of oncologists who use IMRT do so with 25 percent or fewer of their patients.

Further, as mentioned previously, IMRT is used most frequently for prostate and head and neck cancer, and these cancer sites already appear to be covered by most insurance companies.

The proposed mandate may have an impact on those centers that treat a significant number of breast and lung cancer patients with IMRT. However, the extent to which the mandate would impact these providers depends on the percentage of the provider's patients that have insurance coverage from a source that currently limits coverage and the overall diversity of treatments provided at those centers.

e. Administrative and Premium Costs

Data is not available to gauge the administrative costs to insurance companies of HB 1405. However, the median monthly premium estimate is expected to be from \$1.00 to \$2.00 for both individual and group coverage based on a relatively small number of insurance companies responding to a recent BOI survey. This appears to be within the range of the estimated impacts of existing health insurance mandates.

Administrative Expenses of Insurance Companies

Data is not currently collected from insurance companies regarding the potential administrative expenses to implement proposed health insurance mandates. While it is reasonable to assume that companies incur some amount of administrative costs from health insurance mandates, the extent of these costs cannot be determined using existing data sources.

Premium Expenses of Policyholders

BOI annually surveys a sample of Virginia health insurers on the premium impact of proposed mandates. In 2006, 50 companies were surveyed. A relatively small number of health insurance companies estimated monthly premium costs for HB 1405, which may limit the usefulness of the estimates. In addition, estimates varied widely. Table 5 shows the premium estimates reported for both individual and group, standard and optional coverage. The median monthly premium estimates for both individual and group coverage as part of a standard policy is around \$1.00. For optional coverage, the median estimate is \$2.00 per month for both individual and group contracts.

A premium increase of \$1.00 to \$2.00 would result in a monthly premium increase of 0.5 percent to 1.04 percent based on the estimated average monthly premium cost for a single coverage, indi-

vidual contract, as defined in BOI's 2004 report on the financial impact of mandated health insurance benefits. This compares to the premium impacts of existing mandates, which range from 0.10 percent to 4.90 percent for single coverage, individual contracts.

Table 5: Estimated Monthly Premium Impact for HB 1405

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (standard)	5	\$1.00	\$15.58	\$0.36
Individual (optional)	4	\$2.00	\$4.00	\$0.90
Group (standard)	21	\$1.13	\$13.81	\$0.00
Group (optional)	15	\$2.00	\$22.53	\$0.00

Source: Bureau of Insurance survey of 50 health insurance companies, 2006.

f. Total Cost of Health Care

The total cost of health care, at least in the short term, would increase as a result of HB 1405 because IMRT is a more expensive treatment than the alternative radiation therapies, most notably 3D-CRT. However, the extent to which it would increase depends on how much physicians increase their utilization of the treatment, particularly for those cancer sites where it is not currently widely used. Some providers indicate that long-term costs could be mitigated because IMRT could reduce radiation-related morbidity over conventional techniques. However, in the absence of clinical outcome data for IMRT, particularly for breast and lung cancers, it appears premature to speculate on whether long-term costs would be reduced.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Although the proposed mandate is consistent with the role of insurance, it is not clear whether it is needed, at least in the short term, because most insurance companies already provide coverage for the cancer sites where IMRT is most frequently used, and providers seem to be adopting IMRT as the standard of care for these sites. However, lack of a mandate may impede the adoption of this technology for additional cancer sites, particularly if future advances and research provide more evidence that IMRT is a superior form of treatment in situations where it is now considered investigational. However, this brings up an additional consideration—whether it is appropriate for the State to mandate a treatment based on a specific medical technology. As mentioned,

medical technology and research will advance, which may make such a mandate obsolete in the future.

a. Social Need/Consistent With Role Of Insurance

The role of health insurance can be considered as promoting public health, encouraging the use of preventive care, and/or providing financial protection from catastrophic financial expenses for unexpected illness. The proposed mandate is consistent with this role because it would help address the cost of treatment needed for an unexpected illness. It is also consistent with the need for patients to have access to medical treatments deemed necessary by their treating physician.

An additional consideration is whether it is appropriate for the State to mandate a treatment as specific as IMRT. Most health insurance mandates relate to either a general health condition or a broad category of medical services. While narrowly defined mandates exist in Virginia, in the case of at least one mandate, it was later determined that the treatment was an inferior approach for treating the specified condition. As medical technology evolves and research advances, a narrowly defined treatment may become obsolete or inappropriate in future years. Therefore, a mandate for IMRT may not be the best way to ensure patients have access to the latest medical treatments that are deemed necessary by treating physicians, which seems to be the issue of concern.

b. Need Versus Cost

Because IMRT is still an emerging technology, whether the need for a mandate outweighs the cost may be different in the short term than the long term. In the short term, it appears that the need for the proposed mandate does not outweigh potential costs. It appears that the cancer sites where IMRT is used most frequently, such as the prostate and head and neck, are already covered by most health insurance companies. Further, providers already seem to be adopting IMRT as the standard of care for these sites. Therefore, a mandate does not appear necessary and could potentially increase the cost of insurance in the short term.

However, medical experts indicate that future research may give more conclusive evidence that IMRT is a superior treatment option for cancers where it is currently considered investigational by insurance companies, in particular breast and lung cancers. In the absence of the mandate and if insurance companies do not modify their policies to reflect emerging research, the adoption of IMRT for other cancer sites may be impeded by lack of reimbursement. Experts also indicate that there are currently circumstances for

breast and lung cancer patients where IMRT is the best and only option for treatment.

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.

The proposed mandated benefit could be adopted as a mandated offer, though insurance companies indicate that it is unlikely that purchasers would choose this option because they would typically not know at the time they purchase the policy whether the coverage would be needed. However, as mentioned previously, the monthly premium is estimated to increase from approximately \$1.00 to \$2.00 if it were provided as an offer, which seems to indicate that insurance companies would expect some increase in utilization resulting from a mandated offer.

ACKNOWLEDGMENTS

JLARC staff would like to acknowledge the expertise, assistance, and information provided by staff at the Virginia Commonwealth University Massey Cancer Center and staff at the University of Virginia Health System. JLARC would also like to thank Dr. Robert Valdez, President of Valdez and Associates, for his suggestions and expertise as a public health consultant. In addition, JLARC would like to thank the Virginia State Corporation Commission Bureau of Insurance, the Virginia Association of Health Plans, Anthem Blue Cross and Blue Shield, the Department of Human Resources Management, the Department of Health, and the Department of Medical Assistance Services for information and assistance provided.

Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

CHAPTER 413

An Act to amend and reenact §§ [2.2-2503](#) and [30-58.1](#) of the Code of Virginia, relating to staffing of the Special Advisory Commission on Mandated Health Insurance Benefits; Joint Legislative Audit and Review Commission.

[H 614]

Approved March 31, 2006

Be it enacted by the General Assembly of Virginia:

1. That §§ [2.2-2503](#) and [30-58.1](#) of the Code of Virginia are amended and reenacted as follows:

§ [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 ap-

pointed 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.

Proposed Mandated Benefit Requiring Coverage of Intensity Modulated Radiation Therapy (IMRT) for Specified Cancer Sites

HOUSE BILL NO. 1405

Offered January 13, 2006

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 intensity modulated radiation therapy for tumors.

Patrons-- Wittman; Senator: Chichester

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 intensity modulated radiation therapy.*

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 health care services shall provide coverage under such policy or plan for the 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.

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,

2007, 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, nor 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](#), 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. 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.

C. 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.

D. 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.

E. For purposes of applying this section, "insurer" when used in a section cited in subsection A 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 <i>JLARC Criteria*</i>	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	<p>If the legislation seeks to mandate coverage of an additional class of practitioners:</p> <p>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.</p> <p>2) The methods of the appropriate professional organization to assure clinical proficiency.</p>
d. Medical Effectiveness of Provider <i>JLARC Criteria*</i>	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 <i>JLARC Criteria*</i>	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 <i>JLARC Criteria*</i>	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact <i>JLARC Criteria*</i>	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.

Annotated Bibliography

PEER-REVIEWED RESEARCH

General IMRT

Guerro Urbano, MT and Nutting, C (2004). Clinical Use of Intensity-modulated Radiotherapy: part II. *The British Journal of Radiology*, 77: 177-182.

Methodology: Review of existing research. Conclusion: IMRT dose distributions have been shown, for a number of tumor types, to offer potential improvements in clinical outcomes. Planning studies have demonstrated which tumor types have the largest potential gains and small clinical studies are beginning to report short-term outcome data from patients. It is the authors' view that IMRT delivery should remain in the context of clinical trials until such time as these improved dose distributions have proven clinical benefits for patients.

Mell LK, Mehrotra AK, Mundt AJ (2005). Intensity-Modulated Radiation Therapy Use in the U.S., 2004. *Cancer*, 104: 1296-1303.

Methodology: Survey of a random sample of radiation oncologists in the U.S. Conclusion: IMRT use among radiation oncologists in the U.S. has increased significantly since 2002. Standardized guidelines and careful, prospective analyses evaluating its risks and benefits are needed.

Miles E, Clark C, Gurerrero Urbano MT, Bidmead M, Dearnaley D, Harrington K, A'Hern, Nutting C (2005). The Impact of Introducing Intensity Modulated Radiotherapy Into Routine Clinical Practice. *Radiotherapy and Oncology*, 77: 241-246.

Methodology: Comparison of sample of patients receiving IMRT compared to conventional radiotherapy. Conclusion: IMRT currently increases overall planning time, but it has been possible to integrate IMRT smoothly and efficiently into the existing treatment working day. This preliminary study suggests that IMRT could be a routine treatment with efficient use of current radiotherapy resources.

IMRT Use for Breast Cancer

Coles C, Moody A, Wilson C, Burnet N (2005). Reduction of Radiotherapy-induced Late Complications in Early Breast Cancer: The Role of Intensity-modulated Radiation Therapy and Partial Breast Irradiation: Part I - Normal Tissue Complications. *Clinical Oncology*, 17: 16-24.

Methodology: Review of existing research. Conclusion: More advanced radiotherapy techniques, such as IMRT and conformal partial breast irradiation, may improve the therapeutic ratio (an individual's likelihood of risk and benefit) for breast cancer patients.

Coles C, Moody A, Wilson C, Burnet N (2005). Reduction of Radiotherapy-induced Late Complications in Early Breast Cancer: The Role of Intensity-modulated Radiation Therapy and Partial Breast Irradiation: Part II - Radiotherapy Strategies to Reduce Radiation-induced Late Effects. *Clinical Oncology*, 17: 98-110.

Methodology: Review of existing research. Conclusion: Incorporating new approaches to breast radiotherapy, such as IMRT and partial breast irradiation, may result in a reduction in morbidity. There are many dosimetry studies reporting the superiority of IMRT over conventional breast radiotherapy, but there is still a paucity of clinical data regarding patient benefit from these techniques. On-going and proposed randomized trials will need to demonstrate the safety and efficacy of these techniques, and also the cost-effectiveness compared with conventional methods.

Freedman GM, Anderson PR, Li J, Eisenberg DF, Hanlon AL, Wang L, Nicolaou N (2006). Intensity Modulated Radiation Therapy (IMRT) Decreases Acute Skin Toxicity for Women Receiving Radiation for Breast Cancer. *American Journal of Clinical Oncology*, 29: 66-70.

Methodology: Comparison of clinical outcomes of 73 women treated with IMRT between January 2003 through January 2004 with clinical outcomes of 60 control patients treated with conventional radiation therapy from November 1985 through August 2000. Conclusion: IMRT is associated with a decrease in severity of acute desquamation compared with a matched control group treated with conventional radiation therapy. Further study of patient symptoms, quality of life, and cosmesis is needed to evaluate the benefit of IMRT for breast cancer.

Vicini F, Sharpe M, Kestin L, Wong J, Remouchamps V, Martinez A (2004). The Use of Intensity Modulated Radiation Therapy in the Treatment of Breast Cancer: Evolving Definition,

Misdirected Criticism, and Untoward Effects. *International Journal of Radiation Oncology, Biology, and Physics*, 58: 1642-1643.

Methodology: Rebuttal to previously published editorial. Conclusion: Radiation therapy for breast cancer must move forward to meet the needs for more precise delivery. As the radiotherapy community moves to more comprehensively treat the regional lymphatics for potential improvements in survival in breast cancer patients, it seems that current techniques may not be capable of meeting this challenge. The techniques embraced by the authors, including IMRT, are the necessary "stepping-stones" to these more complex applications.

IMRT Use for Lung Cancer

Chapet O, Benedick AF, Ten Haken RK (2006). Multiple Fields May Offer Better Esophagus Sparing Without Increased Probability of Lung Toxicity in Optimized IMRT of Lung Tumors. *International Journal of Radiation Oncology, Biology, and Physics*, 65: 255-265.

Methodology: Dosimetric treatment-planning study utilizing treatment-planning data from eight patients. Conclusion: Optimized many-field IMRT plans can lead to escalated lung-tumor dose in the special case of esophagus overlapping planning tumor volumes, without unacceptable alteration in the dose distribution to the normal lung. Authors indicate that early applications of this technique may be limited to patients capable of tolerating deep inspiration breath-hold maneuvers to minimize organ motion.

Choi Y, Kim JK, Lee HS, Hur WJ, Chai GY, Kang KM (2005). Impact of Intensity-Modulated Radiation Therapy as a Boost Treatment on the Lung-Dose Distributions for Non-Small-Cell Lung Cancer. *International Journal of Radiation Oncology, Biology, and Physics*, 63: 683-689.

Methodology: Comparison of radiation dose plans for seven patients. Conclusion: To keep the beneficial effects of IMRT plans in terms of lung toxicity and dose conformity around a target, it is better to use the IMRT plans over the whole radiotherapy course rather than just for the boost plans. Study also mentions that the role of IMRT for non-small-cell lung cancers is not established and is still being investigated at present.

Holloway C, Robinson D, Murray B, Amanie J, Butts C, Smylie M, Chu K, McEwan AJ, Halperin R, Wilson HR (2004). Results of a Phase I Study to Dose Escalate Using Intensity Modulated Radiotherapy Guided by Combined PET/CT Imag-

ing with Induction Chemotherapy for Patients with Non-Small Cell Lung Cancer. *Radiotherapy and Oncology*, 73: 285-287.

Methodology: Clinical study of five patients. Conclusion: One patient developed grade 5 pneumonitis, which was fatal, and study was halted. It is possible that the synergistic combination of pre-radiation therapy health and treatment side effects led to patient's death.

Mehta M, Scrimger R, Mackie R, Paliwal B, Chappell R, Fowler J (2001). A New Approach to Dose Escalation in Non-Small-Cell Lung Cancer. *International Journal of Radiation Oncology, Biology, and Physics*, 49: 22-33.

Methodology: Analysis of data from previous dose escalation trials reanalyzed. Conclusion: A dose-per-fraction escalation approach in non-small-cell lung cancer should yield superior outcomes compared to standard dose escalation approaches using a fixed dose per fraction. Highly conformal radiotherapy techniques, including IMRT, will be necessary to achieve significant dose-per-fraction escalation without unacceptable morbidity.

Murshed, H, Liu HH, Liao Z, Barker J, Xiaochun W, Tucker S, Chandra A, Guerrero T, Stevens C, Change J, Jeter M, Cox J, Komaki R, Mohan R (2004). Dose and Volume Reduction for Normal Lung Using Intensity-Modulated Radiotherapy for Advanced-Stage Non-Small-Cell Lung Cancer. *International Journal of Radiation Oncology, Biology, and Physics*, 58: 1258-1267.

Methodology: Comparison of IMRT dose plans to patients who previously underwent 3D-CRT. Conclusion: IMRT planning significantly improved target coverage and reduced the volume of normal lung irradiated above low doses. The spread of low doses to normal tissues can be controlled in IMRT with appropriately selected planning parameters. The dosimetric benefits of IMRT for advanced stage non-small-cell lung cancer must be evaluated further in clinical trials.

Liu HH, Wang X, Dong L, Wu Q, Liao Z, Stevens C, Guerrero T, Komaki R, Cox J, Mohan R (2004). Feasibility of Sparing Lung and Other Thoracic Structures with Intensity-Modulated Radiotherapy for Non-Small-Cell Lung Cancer. *International Journal of Radiation Oncology, Biology, and Physics*, 58: 1268-1279.

Methodology: Retrospective treatment planning study comparing IMRT and 3D-CRT. Conclusion: It is possible to reduce the volumes of low dose radiation for thoracic normal tissues using IMRT. IMRT may be applicable for non-small-cell lung cancer. The effi-

cacy and long-term clinical outcome of IMRT should be rigorously investigated before any firm conclusions are drawn.

IMRT Use for Other Cancer Sites

Czito B, Anscher M, Willet C (July 2006). Radiation Therapy in the Treatment of Cholangiocarcinoma. *Oncology*, 20: 873-884.

Methodology: Review of existing research. Conclusion: Despite best efforts, the majority of patients with biliary cancers will succumb to their disease. The integration of novel therapeutic strategies in this disease is indicated. When combined with traditional chemotherapeutic agents and precision radiation techniques such as IMRT, these strategies may improve local control and survival in these patients.

OTHER RESEARCH

Blue Cross Blue Shield Association, Technology Evaluation Center (December 2005). Special Report: Intensity-Modulated Radiation Therapy for Cancer of the Breast and Lung. *Tec Assessment Program*, 20, 13.

Methodology: Review of existing research. Conclusion: No studies were identified (randomized or nonrandomized; prospective or retrospective) that directly compared health outcomes of IMRT with health outcomes of 3D-CRT (using concurrent or historical controls). Available data are insufficient to determine whether IMRT is superior to 3D-CRT for improving health outcomes of patients with breast or lung cancer.

Cancer Consultants.com (2002). Current Topics in Oncology 2002L Intensity Modulated Radiation Therapy.

Methodology: Review of existing research. Conclusion: At present time, it appears that IMRT will or has replaced 3D-CRT where appropriate. It is unlikely that there will be any significant number of formal randomized trials to confirm the superiority of IMRT over other technology. Most major radiation oncology centers believe this technique to be superior and have already invested heavily in it.

Galician Agency for Health Technology Assessment (2005). HTA Record 20050345: Intensity Modulated Radiotherapy. *Health Technology Assessment Database*.

Methodology: Review of existing research. Conclusion: The scientific evidence on the effectiveness and security of IMRT in comparison with the conformed radiotherapy is scarce and of low quality, which limits establishment of rigorous conclusions. Prospective

comparative studies are necessary to value the effectiveness and cost-effectiveness of IMRT.

Trinity Health (2003). Emerging Trends and Technologies Report: Intensity-Modulated Radiation Therapy. August 27, 2003.

Evidence clearly illustrates that IMRT advances radiation therapy by minimizing harm to nearby structures and increasing radiation intensity to cancerous tumors. Research also shows that to maximize the benefits of IMRT, several factors must be in place.



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