REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

SENATE BILL 870 MANDATED COVERAGE FOR PROPHYLACTIC SURGERIES

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2004

January 6, 2004

To: The Honorable Mark R. Warner
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 Senate Bill 870 regarding a proposed mandate of coverage for prophylactic surgeries.

Respectfully submitted,

Stephen H. Martin
Chairman
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TABLE OF CONTENTS

INTRODUCTION

The 2003 Senate Committee on Commerce and Labor referred Senate Bill 870 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). Senate Bill 870 is patroned by Senator R. Creigh Deeds.

The Advisory Commission held a public hearing on September 15, 2003 in Richmond to receive public comments on Senate Bill 870. In addition to the bill's chief patron, three interested parties spoke in favor of Senate Bill 870. Two cancer survivors, who had successfully undergone a prophylactic procedure to prevent cancer, provided testimony in support of the proposed legislation. The third speaker was a physician, and a retired professor of biomedical ethics and internal medicine. One individual representing the Virginia Association of Health Plans (VAHP) spoke in opposition to the proposed legislation.

In addition, the Advisory Commission received three letters in support of, and two letters in opposition to, the proposed mandate.

SUMMARY OF PROPOSED LEGISLATION

Senate Bill 870 was introduced by Senator R. Creigh Deeds in the 2003 General Assembly Session. Senate Bill 870 applies to 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; (ii) corporations providing individual or group accident and sickness subscription contracts; or (iii) health maintenance organizations providing a health care plan for health care services. The bill prohibits insurers from excluding or refusing to provide coverage for prophylactic surgical procedures and medical services directly related to such procedures; in cases where (a) the covered person's treating physician has determined that the person has a genetic factor or family history indicating a predisposition to a difficult-to-diagnose pathology, (b) the risks to the covered person of developing the difficult-to-diagnose pathology as a result of such person's predisposition render the provision of prophylactic surgical procedures and medical services directly related to such procedures to be medically appropriate, and (c) coverage for treatment of the difficult-to-diagnose pathology would be provided under the terms of the policy, contract or plan if the difficult-to-diagnose pathology had been diagnosed.

"Difficult-to-diagnose pathology" means a disease, such as but not limited to, breast cancer or ovarian cancer, that is asymptomatic or otherwise not susceptible to diagnosis until reaching a stage at which the likelihood of successful treatment is significantly less than it would be had the treatment been performed when the disease was asymptomatic or not susceptible to diagnosis. "Prophylactic surgical procedure" means a mastectomy, hysterectomy, or similar

surgical procedure, when performed prior to the diagnosis of or presentation of symptoms of a difficult-to-diagnose pathology, in order to prevent, eliminate or reduce the likelihood of the development of the difficult-to-diagnose pathology.

PRIOR ADVISORY COMMISSION REVIEW

Senator Deeds was the patron of Senate Bill 619 in the 2002 General Assembly Session. Senate Bill 619 was reviewed by the Advisory Commission in 2002. Senate Bill 619 was similar to Senate Bill 870, and prohibited insurers and HMOs from excluding coverage for services to prevent, eliminate, or reduce the likelihood of the development of an illness, disease, or condition for which coverage is provided solely on the grounds that signs or symptoms of the illness, disease, or condition have not yet presented. Coverage was to be provided if the patient's treating physician had determined that the patient had a genetic factor or family history indicating a predisposition to the illness, disease or condition and that risk to the patient make the services medically appropriate.

The Advisory Commission recommended against the enactment of Senate Bill 619. The Advisory Commission members noted the merits of the bill, but believed the language was too broad. Members also believed the bill would increase the cost of health insurance through higher premiums that would be passed on to consumers.

SOCIAL IMPACT

The proposed legislation seeks to cover prophylactic surgical procedures for several conditions where the insured's physician has determined a genetic predisposition due to family history of a difficult-to-diagnose pathology. The National Institutes of Health Website explains that most genetic disorders are "multifactorial inheritance disorders," meaning they are caused by a combination of small variations in genes, often in concert with environmental factors. Research done on the human genome has found that many common diseases usually caused by genetic alterations in the genes of an individual's cells (such as breast cancer and colon cancer) have rare hereditary forms. In these cases, gene variants that cause or strongly predispose a person to these cancers run in a family and significantly increase each member's risk of developing the disease.[i]

Among the most strongly linked genetic disorders are cancers, including breast cancer, ovarian cancer, colon cancer, prostate cancer, and skin cancer. Some other diseases that are genetically linked include cystic fibrosis, Parkinson's disease, Huntington's disease, sickle cell disease, and progeria. [ii]

Senate Bill 870 specifically lists two diseases in its definition of difficult-to-diagnose pathology, breast cancer and ovarian cancer.

GENETIC TESTING

The National Institutes of Health describes gene testing as looking for "abnormalities in a person's genes, or the presence/absence of key proteins whose production is directed by specific genes." The abnormalities in either the proteins or genes could indicate an inherited disposition to a disorder. Genetic testing includes gene tests (DNA testing) and biochemical tests (protein testing).

In gene tests, DNA within cells taken from a person's blood, body fluids or tissues is examined to look for abnormalities that flag a disease or disorder. The abnormality can be relatively large or very small, ranging from a piece of a chromosome, or even an entire chromosome, missing or added (large) to as little as one extra, missing or altered chemical base within the DNA strand. Genes can be amplified (too many copies), over-expressed (too active), inactivated, or lost altogether. Sometimes pieces of chromosomes can become switched, transposed or discovered in an incorrect location.

A variety of techniques are used in gene tests to examine a person's DNA. Some tests involve using probes (short strings of DNA) with base sequences that are complementary to those of the mutated gene. These probes will seek their complements within an individual's genome. If the mutated sequence is present in the patient's genome, the probe will find it and bind to it, flagging the mutation.[iii]

Genetic testing can be predictive, discovering whether an individual has an inherited disposition to a certain disease, before symptoms appear. Genetic tests can also confirm a diagnosis if symptoms are present. Tests can determine whether a person is a carrier for the disease. Carriers will not develop the disease, but can pass on the faulty gene to their children. Prenatal testing can help expectant parents know whether their unborn child will have a genetic disease or disorder. Newborn screening tests infants for abnormal or missing gene products. [iv]

Individuals in families at high risk for a disease live with troubling uncertainties about their own future and that of their children. A negative test - especially one that is strongly predictive - can provide an enormous sense of relief. A positive test can also produce benefits. In the best circumstances, a positive test enables the person to take steps to reduce risk. These steps could include regular screening for the disease or lifestyle changes, such as a change in diet or regular exercise. A positive test can relieve uncertainty, and can enable people to make informed decisions about their future. [v]

Ovarian Cancer

Ovarian cancer occurs when a malignant tumor begins in the ovaries. There are several types of ovarian cancer. Ovarian cancer that begins on the surface of the ovary (epithelial carcinoma) is the most common type. Ovarian cancer cells can break away from the ovary and spread to other tissues and organs in a process called shedding. When ovarian cancer sheds, it tends to seed (form new tumors) on the peritoneum (the large membrane that lines the abdomen) and on the diaphragm (the thin muscle that separates the chest from the abdomen). Fluid may collect in the abdomen. This condition is known as ascites. It may make a woman feel bloated, or her abdomen may look swollen.[vi]

Ovarian cancer cells can also enter the bloodstream or lymphatic system (the tissues and organs that produce and store cells that fight infection and disease). Once in the bloodstream or lymphatic system, the cancer cells can travel and form new tumors in other parts of the body.[vii]

Ovarian cancer is the fifth most common cancer (other than skin cancer) in women. It ranks fifth as the cause of cancer death in women. The American Cancer Society estimates that there will be about 25,400 new cases of ovarian cancer in this country in 2003. About 14,300 women will die of the disease. But, the number of new cases of ovarian cancer has been going down since 1991. [viii] The estimated number of deaths from ovarian cancer in Virginia in 2002 was 300. [ix]

The exact cause of ovarian cancer is not known, but ovarian cancer risk is higher among women whose close blood relatives (mother, sister, and daughter) have this disease. The risk of blood relatives can be from either the mother's or father's side of the family. There is a higher risk if ovarian cancer happened at an early age. About 1 in 10 cases of ovarian cancer are linked to gene changes that can be found with certain tests. These changes are linked to an increased risk of breast and colorectal cancer.[x]

Breast Cancer

Breast cancer is a malignant (cancerous) tumor that starts from cells of the breast. The disease occurs most in women, but men can get breast cancer as well. The breast itself is made up of lobules, ducts, fatty and connective tissue, blood vessels, and lymph vessels. Lymph vessels are like veins, except that they carry lymph fluid instead of blood.

Lymph is a clear fluid that contains immune system cells and tissue waste products. The fluid is carried in lymph vessels that lead to small, pea-sized

collections of tissue called lymph nodes. Most lymphatic vessels of the breast lead to lymph nodes under the arm, which are called axillary nodes.

When breast cancer cells reach the underarm lymph nodes and continue to grow, they cause the nodes to swell. Once cancer cells have reached these nodes, they are more likely to spread to other organs of the body as well. [xi]

The American Cancer Society reports that about 211,300 women in the United States will be found to have invasive breast cancer in 2003. About 39,800 women will die from the disease. Breast cancer death rates declined significantly from 1992 to 1996, with the largest decrease in younger women--both white and black. This decline is probably the result of earlier detection and improved treatment.[xii]

Information presented to the Advisory Commission indicates that the estimated new cases of breast cancer in Virginia in the year 2002 was 5,000. The estimated number of deaths from breast cancer in Virginia in 2002 was 1000. [xiii]

The exact cause of breast cancer is also not known. However, there are several factors that cannot be changed and link people with breast cancer. If a woman has inherited a changed gene from either parent, she is more likely to develop breast cancer. About 5 to 8 women out of 10 with these gene changes will develop breast cancer during their lifetime. Another genetic risk factor is linked to mutations in certain genes, such as the BRCA1 or BRCA2 genes, which are genes linked to breast cancer and ovarian cancer. About 1 in 10 cases of breast cancer are linked to gene mutations. [xiv]

Colorectal Cancer

The American Cancer Institute describes colon and rectal cancer as a cancer that develops in the digestive system, which is also called the gastrointestinal, or GI, system. The wall of the sections of the colon and rectum has several layers of tissue. Colorectal cancers start in the innermost layer and can grow through some or all of the other layers.

Colorectal cancers are thought to develop slowly over a period of several years. We now know that most colorectal cancers begin as a *polyp,* also known as an *adenoma.* Over many years (usually about 5 to 10), these polyps can slowly change into cancer. A polyp is a mass of tissue that grows into the center of the tube that makes up the colon or rectum. Some types of polyps (inflammatory polyps) are not precancerous. But, having adenomatous polyps increases your risk of developing cancer, especially if you have many polyps or if they are large.[xv]

Aside from skin cancer, colorectal cancer is the third most common cancer found in men and women in the United States. The American Cancer Society estimates that there will be about 105,500 new cases of colon cancer and 42,000

new cases of rectal cancer in 2003 in the United States. They will combine to cause about 57,100 deaths. [xvi]

Information presented to the Advisory Commission indicates that the estimated new cases of colon and rectal cancer in Virginia in the year 2002 were 3,500. The estimated number of deaths from colon and rectal cancer in Virginia in 2002 was 1,400. [xvii]

PROPHYLACTIC SURGERIES

The National Cancer Institute describes a prophylactic mastectomy as the "surgical removal of one or both breasts in an effort to prevent or reduce the risk of breast cancer. Total mastectomy, an operation to remove the entire breast and nipple, is the procedure of choice. Subcutaneous mastectomy, an operation to remove the breast tissue but spare the nipple, is recommended less often because of the possibility of leaving cancerous breast tissue behind." [xviii]

The National Cancer Institute reports that a preventive mastectomy may be considered for several reasons. Women who have already had one breast removed due to cancer may consider this procedure in an effort to avoid developing a new cancer in the other breast. Preventive mastectomy may also be an option for women with a strong family history of breast cancer, especially if several close relatives developed the disease before age 50. Women in families with hereditary breast cancer who test positive for a known cancer-causing gene alteration may also consider this surgery.

Although having a preventive mastectomy can reduce the risk, no one can be certain that this procedure will protect a woman from breast cancer. It is impossible for a surgeon to remove all breast tissue, and breast cancer can still develop in the small amount of remaining tissue. The information noted that all women are different, so the procedure should be considered in the context of each woman's unique risk factors and her level of concern. [xix]

A prophylactic oophorectomy (also known as a prophylactic hysterectomy) is the removal of both healthy ovaries. The American Cancer Society suggests this procedure should be done at the same time as a hysterectomy. [xx]

CURRENT INDUSTRY PRACTICES

The State Corporation Commission's Bureau of Insurance surveyed sixty of the top writers of accident and sickness insurance in Virginia in April 2003, regarding the bills to be reviewed by the Advisory Commission. Fifty companies responded by the deadline. Thirteen companies indicated that they have little to no, applicable health insurance business in force in Virginia. These thirteen companies write few, if any, policies that are subject to insurance mandates. Of the remaining 37 companies, sixteen companies reported that they provided the coverage required by Senate Bill 870, under their standard benefit package.

Twenty-one companies said they did not provide the coverage. Two of the companies that responded that they did provide coverage, noted that the coverage was limited to prophylactic mastectomies.

FINANCIAL IMPACT

Fourteen companies provided cost estimates of premiums for providing the coverage for Senate Bill 870. The companies provided cost figures of between $.03 and $1.67 per month per standard individual policy. Cost figures were between $.02 and $2.01 per month per standard group certificate, to provide the coverage required by Senate Bill 870. One company reported the cost to be .1%. Insurers providing estimates for coverage on an optional basis provided cost figures from $.05 to $8.35 per month per standard individual policy, and between $.03 to $5.01 per month, per standard group certificate.

Cost estimates were provided after the public hearing and final recommendation for Senate Bill 870. A large insurance carrier estimated the costs of the prophylactic procedures associated with the proposed legislation, based on research from its medical staff. The company estimated that a prophylactic mastectomy costs approximately $12,000, a prophylactic colectomy costs approximately $20,000, and a prophylactic oophorectomy costs approximately $9,000.

SIMILAR LEGISLATION IN OTHER STATES

Information from the National Association of Insurance Commissioners, the National Insurance Law Services, and a survey of state insurance departments was reviewed to determine if requirements similar to Senate Bill 870 exist in other states. Based on the information available to staff, no other states have enacted legislation that is similar to Senate Bill 870. Also, none of the states currently have similar provisions introduced in their respective legislative systems.

REVIEW CRITERIA

SOCIAL IMPACT

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

The American Cancer Society estimates that there will be about 25,400 new cases of ovarian cancer in this country in 2003. About 14,300 women will die of the disease, but the number of new cases of ovarian cancer has been going down since 1991. [xxi] The estimated number of deaths from ovarian cancer in Virginia in 2002 was 300. [xxii]

The American Cancer Society reports that about 211,300 women in the United States will be found to have invasive breast cancer in 2003. About 39,800 women will die from the disease. Breast cancer death rates declined significantly from 1992 to 1996, with the largest decrease in younger women--both white and black. This decline is probably the result of earlier detection and improved treatment.[xxiii] Information presented to the Advisory Commission indicates that the estimated new cases of breast cancer in Virginia in the year 2002 were 5,000. The estimated number of deaths from breast cancer in Virginia in 2002 was 1000. [xxiv]

The American Cancer Society estimates that there will be about 105,500 new cases of colon cancer and 42,000 new cases of rectal cancer in 2003 in the United States. They will combine to cause about 57,100 deaths. [xxv] Information indicates that the estimated new cases of colon and rectal cancer in Virginia in the year 2002 were 3,500. The estimated number of deaths from colon and rectal cancer in Virginia in 2002 was 1,400. [xxvi]

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

The State Corporation Commission's Bureau of Insurance surveyed sixty of the top writers of accident and sickness insurance in Virginia in April 2003, regarding the bills to be reviewed by the Advisory Commission. Fifty companies responded by the deadline. Thirteen companies indicated that they have little to no, applicable health insurance business in force in Virginia. These thirteen companies write few, if any, policies that are subject to insurance mandates. Of the remaining 37 companies, sixteen companies reported that they provided the coverage required by Senate Bill 870, under their standard benefit package. Twenty-one companies said they did not provide the coverage. Two of the responding companies indicated that they did provide coverage, but noted that the coverage was limited to prophylactic mastectomies.

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.

Proponents argue that if there is no coverage for the treatments, there is a possibility that individuals who receive treatments later would be receiving treatment too late. The bill seeks to require coverage of prophylactic surgical procedures for several conditions where the insured's physician has determined that the patient has a genetic predisposition to a disease or condition due to family history of a difficult-to-diagnose pathology. Proponents argued that if a person is found to be genetically predisposed or has a strong family history, then he or she should have the prophylactic surgery to prevent the disease from advancing. Many times people wait too long due to lack of coverage, until a

physician has discovered symptoms of the disease, before it can treated and covered by insurance.

The opponents of this bill representing insurance companies stated that most insurance companies already cover genetic testing. They also stated that many prophylactic procedures are also covered. However, the necessity for surgery is evaluated by the insurance company on a case-by-case basis.

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.

Proponents suggest that if the coverage were not made available, then individuals would have to pay out-of-pocket for surgery done before symptoms appear. They argue that insurance will not cover the procedure until it has been diagnosed or symptoms are visible. Therefore, if patients felt the need for the procedure without coverage, then there would be considerable financial hardships on the patient. Such financial hardship would include hospital costs, surgeon fees, and other fees associated with the procedures.

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

Although the exact level of public demand is not known, there is information from the American Cancer Society that suggests the number of individuals that might benefit from, or be interested in, prophylactic surgeries. The American Cancer Society reported that the estimated new cases of breast and colorectal cancers in Virginia in 2002, were 5,000 and 3,500 cases respectively. The American Cancer Society also estimated that in Virginia in 2002, 300 people died as a result of ovarian cancer.

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

A physician and retired professor of biomedical ethics and internal medicine spoke at the public hearing for Senate Bill 870. The physician believes the proposed legislation is in accordance with the genetic discrimination bill passed by the General Assembly, which, in his opinion, was aimed at the use of genetic testing to discover cancers. He supported the use of prophylactic procedures which can save or extend lives by treating the disease before it forms or spreads. He also believed prophylactic surgeries could save insurers money later when expensive cancer treatments, such as chemotherapy or radiation, would be necessary to fight the cancer.

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

No information was received from collective bargaining organizations addressing potential interest in negotiating privately for inclusion of this coverage in group contracts.

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.

No information was received from the appropriate health planning agency or health system on the social impact of the proposed mandate.

FINANCIAL IMPACT

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

Several proponents suggested that prophylactic surgeries are a life-saving tool as well as a cost containment tool for insurance companies. They believe that by having a prophylactic procedure, much of cancer therapy costs, such as chemotherapy and radiation treatment, would be saved. One proponent testified that she had breast cancer, and her physician indicated that she was also predisposed to ovarian cancer. He advised her to have prophylactic surgery to remove her ovaries, which cost approximately $1,300. It was her belief that had she not paid to remove her ovaries, her insurance companies would have been paying for ultrasounds ($200) and blood testing ($150) every six months. She argued that if her ovaries were intact, the overall costs of blood tests and ultrasounds over the next ten years would have totaled $7,000. She concluded that the $1,300 for removal of her ovaries, a potential life saving procedure, was a $5,700 savings to insurance companies.

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

Appropriate use is expected to increase as insureds that meet the medical requirements of the bill decide with their physician to have the prophylactic surgeries.

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

Proponents argue that the alternative to the mandated treatment would be inheriting the disease or not preventing disease in a timely manner. They argued that many insurance companies do not cover prophylactic surgeries until

diagnosis or symptoms of the disease occur, which, they argue, is often too late for effective treatment. They also argued that prophylactic surgeries are too expensive for people to pay out-of-pocket; therefore, the alternative is to not receive treatment.

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 not expected that the number and type of providers over the next five years would be significantly affected if the treatment were mandated.

e. The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

Fourteen companies provided cost estimates of premium prices for providing the coverage for Senate Bill 870. Respondents to the survey provided cost figures of between $.03 and $1.67 per month per standard individual policy. Cost figures of between $.02 and $2.01 per month per standard group certificate were estimated for providing the coverage required by Senate Bill 870. One company reported the cost to be .1%. Seven companies providing cost figures for coverage on an optional basis estimated cost figures from $.05 to $8.35 per month per standard individual policy, and nine companies estimated between $.03 to $5.01 per month, per standard group certificate.

Opponents argued that the proposed coverage is too broadly worded, and it could require insurers to cover a great number of services. They also stated that it would be nearly impossible for health plans to predictably price the benefit, and they believed the resulting fiscal impact would be immense.

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

Opponents from the insurance industry suggest that coverage of mandated health insurance mandates has a direct link to a rise in health insurance premiums. The unifying theme of their comments was that with the addition of each mandate, there will be an increase of the premiums in the insurance market. This would; in the opinion of opponents, would cause health insurance to be unaffordable for more Virginians, with the greatest impact upon small businesses and those who pay for their own health insurance.

One opponent stated, in writing, that cost containment in health care (from a recent survey) was the number one priority of businesses. The opponent explained that health care costs, coupled with a sluggish economy, cause employers to rethink how they provide health care coverage and what health care benefits they can provide to employees. Because of higher health care

costs, employers are shifting more of the health care coverage costs onto employees through higher deductibles, higher copayments, fewer or no benefits, and premium shifting. The opponent stated his opinion that mandating health care benefits, such as is the case with the proposed legislation, causes the total cost of health care to rise.

MEDICAL EFFICACY

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

The National Cancer Institute describes a prophylactic mastectomy as the "surgical removal of one or both breasts in an effort to prevent or reduce the risk of breast cancer. Total mastectomy, an operation to remove the entire breast and nipple, is the procedure of choice. Subcutaneous mastectomy, an operation to remove the breast tissue but spare the nipple, is recommended less often because of the possibility of leaving cancerous breast tissue behind." [xxvii]

The National Cancer Institute reports that a preventive mastectomy may be considered for several reasons. Women who have already had one breast removed due to cancer may consider this procedure in an effort to avoid developing a new cancer in the other breast. Preventive mastectomy may also be an option for women with a strong family history of breast cancer, especially if several close relatives developed the disease before age 50. Women in families with hereditary breast cancer who test positive for a known cancer-causing gene alteration may also consider this surgery.

Although having a preventive mastectomy can reduce the risk, no one can be certain that this procedure will protect a woman from breast cancer. It is impossible for a surgeon to remove all breast tissue, and breast cancer can still develop in the small amount of remaining tissue. The information noted that all women are different, so the procedure should be considered in the context of each woman's unique risk factors and her level of concern. [xxviii]

A prophylactic oophorectomy (also known as a prophylactic hysterectomy) is the removal of both healthy ovaries. The American Cancer Society suggests this procedure should be done at the same time as a hysterectomy. [xxix]

Recent articles from the New England Journal of Medicine were submitted to the Advisory Commission. The articles concluded that prophylactic surgeries could prevent other cancers from forming. In all the studies, women had mutations in the BRCA1 or BRCA2 genes, which have been linked to breast and ovarian cancers.

The first study followed two groups of women 35 years of age or older. One group of women chose to have a salpingo-oophorectomy, and another group of women elected to not have the prophylactic surgery and to solely be surveillanced. (follow-up was approximately 2 years) The findings were that of the 98 women who chose the prophylactic oophorectomy, 3 were diagnosed with breast cancer, and one was diagnosed with peritoneal cancer. Of the 72 women who chose surveillance, breast cancer was diagnosed in 8, ovarian cancer in 4, and peritoneal cancer in 1.[xxx]

The second study researched 551 women who had BRCA1or BRCA2 gene mutations. The follow-up in this study was at least 8 years. In this similar study, 259 women underwent a bilateral oophorectomy, and 292 did not undergo the surgery. Of the 259 women who elected prophylactic oophorectomy, 6 women were diagnosed with ovarian cancer at the time of surgery, and 2 women were diagnosed with peritoneal cancer 8.6 years after the surgery. Of the 292 women who elected no prophylactic surgery, 58 women were diagnosed with ovarian cancer.[xxxi]

In a third related study, 241 women were researched for the occurance of breast cancer for women who had a bilateral oophorectomy. The follow-up in this study was at least 8 years. Of the 99 women who underwent the prophylactic procedure, 21 (just over 21%) were diagnosed with breast cancer. Of the 142 women who elected not to have the prophylactic oophorectomy, 60 (or 42.3%) were diagnosed with breast cancer.[xxxii]

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 a medical and broader social need will be addressed by helping those who have a genetic predisposition or family history to a certain disease or illness. They argue that a social need will be met for the thousands of patients who could possibly become terminally ill by a disease such as cancer. They argue that the proposed legislation would pre-treat or prevent any physical pain and suffering from a diagnosis and symptom of a cancer with a prophylactic surgery, and that patient's lives will be saved by reducing any chance of a life-threatening cancer or disease forming in their bodies. Therefore, proponents believe the bill is consistent with role of health insurance.

Opponents noted that genetic testing has tremendous potential to the insights on the incidence and prevalence of diseases. They noted that genetic information may eventually enhance the ability to diagnose accurately and to cure such diseases. They do not believe that the bill will be 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.

Fourteen companies provided cost estimates of premium prices for providing the coverage for Senate Bill 870. Respondents to the survey provided cost figures of between $.03 and $1.67 per month per standard individual policy, and between $.02 and $2.01 per month per standard group certificate, to provide the coverage required by Senate Bill 870. One company reported the cost to be .1%. Seven companies providing cost figures for coverage on an optional basis estimated cost figures from $.05 to $8.35 per month per standard individual policy, and nine companies estimated between $.03 to $5.01 per month, per standard group certificate.

Several proponents suggested that prophylactic surgeries are a life-saving tool as well as a cost containment tool for insurance companies. They believe that by having prophylactic procedures, much of cancer therapy costs, such as blood work, lab costs, chemotherapy and radiation treatment, would be eliminated. This would save insurance companies who have to pay for treatment of the disease once it is diagnosed.

Opponents argued that the proposed coverage is too broadly worded, and it could require insurers to cover a great number of services. They also stated that it would be nearly impossible for health plans to predictably price the benefit and they believed the fiscal impact would be immense.

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 insureds.

RECOMMENDATION

The Advisory Commission voted unanimously (9-0) on November 17, 2003 to recommend against the enactment of Senate Bill 870.

CONCLUSION

Senate Bill 870 would require coverage for prophylactic surgeries where a person had a family history or genetic predisposition to a disease or illness. The Advisory Commission believed that there is significant research that suggests that certain cancers are genetically predisposed in families. They also believe that a broader social, financial, and medical impact would be met by requiring coverage of prophylactic surgeries to avoid the formation of the genetically linked cancers. However, the Advisory Commission still believed that the wording of the proposed legislation is too broad. Advisory Commission members indicated a willingness to favorably vote upon on an amended version that would have narrowed the scope of the proposed legislation to prophylactic surgeries for the cancers which have been found to be genetically linked. However, amended language was not submitted to the Advisory Commission.

References

[i] Frequently Asked Questions About Genetics. August 2003. National Institutes of Health Website. www.nih.gov

[ii] Frequently Asked Questions About Genetics. August 2003. National Institutes of Health Website. www.nih.gov

[iii] Frequently Asked Questions About Genetics. August 2003. National Institutes of Health Website; National Human Genome Research Institute. www.genome.com

[iv] Frequently Asked Questions About Genetics. August 2003. National Institutes of Health Website; National Human Genome Research Institute. www.genome.com

[v] Frequently Asked Questions About Genetics. August 2003. National Institutes of Health Website; National Human Genome Research Institute. www.genome.com

[vi] What You Need to Know About Ovarian Cancer. August 2003. National Cancer Institute Website. www.cancer.gov.

[vii] What You Need to Know About Ovarian Cancer. August 2003. National Cancer Institute Website. www.cancer.gov.

[viii] Overview: Ovarian Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[ix] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[x] Overview: Ovarian Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xi] Overview: Breast Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xii] Overview: Breast Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xiii] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[xiv] Overview: Breast Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xv] Overview: Colon Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xvi] Overview: Colon Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xvii] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[xviii]Cancer Facts; Preventive Mastectomy. August 2003. National Cancer Institute Website. www.cancer.gov

[xix] Cancer Facts; Preventive Mastectomy. August 2003. National Cancer Institute Website. www.cancer.gov

[xx]Can Ovarian Cancer Be Prevented? August 2003. American Cancer Society Website. www.cancer.org

[xxi] Overview: Ovarian Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xxii] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[xxiii] Overview: Breast Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xxiv] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[xxv] Overview: Colon Cancer. August 2003. American Cancer Society Website. www.cancer.org.

[xxvi] American Cancer Society. Mid-AtlanticDivision; Cancer Facts and Figures 2002. New Castle; Amer.Cancer Soc., 2002.

[xxvii]Cancer Facts; Preventive Mastectomy. August 2003. National Cancer Institute Website. www.cancer.gov

[xxviii] Cancer Facts; Preventive Mastectomy. August 2003. National Cancer Institute Website. www.cancer.gov

[xxix]Can Ovarian Cancer Be Prevented? August 2003. American Cancer Society Website. www.cancer.org

[xxx] Risk-Reducing Salpingo-Oophorectomy in Women with BRCA1or BRCA2 Mutation. May 23, 2002. New England Journal of Medicine, Vol.346, No, 21.

[xxxi]Prophylactic Oopherectomy in Carriers of BRCA1 or BRCA2 Mutations. May 23, 2002. New England Journal of Medicine, Vol.346, No, 21.

[xxxii] Prophylactic Oopherectomy in Carriers of BRCA1 or BRCA2 Mutations. May 23, 2002. New England Journal of Medicine, Vol.346, No, 21.