

REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

SENATE BILL 619
MANDATED COVERAGE FOR PREVENTION,
ELIMINATION OR REDUCTION IN ILLNESS, DISEASE
OR CONDITION DUE TO GENETIC PREDISPOSITION
OR FAMILY HISTORY PRIOR TO PRESENTATION OF
SYMPTOMS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2003

December 16, 2002

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 619 that mandates coverage for the prevention, elimination or reduction in illness, disease or condition due to genetic predisposition or family history prior to the presentation of symptoms.

Respectfully submitted,

Stephen H. Martin
Chairman
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INTRODUCTION

The Senate Committee on Commerce and Labor referred Senate Bill 619 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) in 2002. The bill was introduced in the General Assembly by Senator R. Creigh Deeds.

The Advisory Commission held a public hearing in Richmond on October 10, 2002, to receive public comments on Senate Bill 619. In addition to the patron, a physician from the University of Virginia Cancer Clinic, a private citizen, and a representative of the Virginia Consumer Action Society for Multiple Sclerosis spoke in favor of the bill.

Three parties spoke in opposition to the bill. Those opposing the bill were representatives of the VAHP, Trigon Blue Cross Blue Shield, and the National Federation of Independent Businesses. Public comments on the high cost of health care coverage were offered by the Virginia Association of Free Clinics.

Written comments in support of the bill were received from the American Cancer Society, two physicians and 13 consumers. Comments in opposition to the bill were received from the VAHP, the Health Insurance Association of America (HIAA), the Virginia Chamber of Commerce, Trigon Blue Cross Blue Shield and the National Federation of Businesses.

The Advisory Commission concluded its review of the bill on November 12, 2002.

SUMMARY OF PROPOSED LEGISLATION

Senate Bill 619 would add Section 38.2-3407.5:2 to the accident and sickness provisions in Title 38.2 of the Code of Virginia. The bill prohibits (i) insurers issuing individual and group accident and sickness policies providing medical and surgical or major medical coverage on an expense-incurred basis; (ii) corporations providing individual or group subscription contracts; and (iii) health maintenance organizations (HMOs) providing health care plans from excluding coverage for services to prevent, eliminate or reduce the likelihood of the development of an illness, disease or condition. The exclusion cannot be based solely on the grounds that signs or symptoms of the disease or condition have not yet presented if the coverage is provided under the policy, contract, or plan. Coverage for the services must be provided if the treating physician determines that the person has a genetic factor or family history that indicates a predisposition to the illness, disease or condition. The physician must determine that the risks from the predisposition make the services medically appropriate.

The bill does not apply to short-term travel, accident only, limited or specified disease policies, or contracts designed for people eligible for Medicare or similar coverage under state or federal plans, or short-term nonrenewable policies of not more than six months' duration.

The bill, as introduced, would apply to contracts, policies or plans delivered, issued for delivery, or renewed in Virginia on and after July 1, 2002.

SOCIAL IMPACT

The proposed legislation appears to cover a number of conditions and illnesses and would require treatments for an illness, disease or condition if there were a genetic factor or family history indicating a predisposition. Many scientists believe that there is evidence that many human afflictions have a genetic component. Genes that relate to early onset breast cancer, ovarian cancer, cystic fibrosis, Huntington's disease, hereditary colon cancer, and the most common form of skin cancer have been identified.

Senate Bill 619 appears to include a number of conditions exhibited by infants as well as those mentioned above. Infants are often screened for many genetic diseases at birth including (i) hypothyroidism, (ii) galactosemia, (iii) phenylketonuria (PKU), (iv) hemoglobinopathies, and (v) congenital adrenal hyperplasia.

Hypothyroidism is an inadequate production of the hormone thyroxine. It can lead to mental and growth retardation. The disease occurs in approximately 1 in 5,000 births.

Galactosemia is a condition that occurs when the body cannot break down galactose (a milk sugar) because the child lacks a specific enzyme. Complications from this condition can be life-threatening. Infants with this condition should have a diet that is low in galactose. One out of seventy-five thousand newborns has this condition.

PKU is a disease that can cause brain damage. Newborns have this condition at a rate of 1 out of 12,000.

Hemoglobinopathies are diseases that affect the amount of hemoglobin that an individual has in his red blood cells. Hemoglobin is the pigment that gives red blood its color and takes oxygen from the lungs to the rest of the body. One of the most common hemoglobinopathies is sickle cell anemia. Misshapen red blood cells clog blood vessels and prevent oxygen from being carried to the body. The condition affects 1 in 450 African-American children and is also found in Asians, Caucasians, and Hispanics.

Congenital adrenal hyperplasia results from an enzyme deficiency. Babies with the condition vomit and develop severe dehydration. It can be life-threatening. It occurs in 1 of every 14,000 newborns. After screenings uncover this genetic disease, the children are treated to prevent damage to their health.

A review of medical literature indicated a number of prophylactic treatments that could possibly be covered by Senate Bill 619. A representative of the VAHP cited information from the European Directory of DNA laboratories that included services for 580 genetic conditions. The primary focus of the legislation appears to be treatments for cancer in areas where research has identified a genetic predisposition. The majority of information that was reviewed related to cancer when prophylactic surgery can be considered an option. Other treatment options for these conditions include cancer screenings and medications. A number of cancer screenings are already mandated for insurance coverage, including coverage for mammograms (Section 38.2-3418.1), coverage for pap smears (Section 38.2-3418.1:2), coverage for PSA testing (Section 38.2-3418.7), and coverage for colorectal cancer screenings (Section 38.2-3418.7:1). Coverage for medications on an outpatient basis is typically based on the payment by the insured for prescription drug coverage.

CANCER PREVALENCE RATES

The American Cancer Society's (ACS) publication "Cancer Facts and Figures 2001" estimated that 30,500 new cancer cases would develop in Virginia, and breast cancer would affect 4,600 Virginians. The ACS further anticipated there would be 3,200 new cases of colon and rectal cancer, 300 ovarian cancer deaths, and 800 prostate cancer cases. The ACS estimated that 5% to 10% of breast cancer cases, 5% of colorectal cancer cases, and 10% of ovarian cancer cases are the result of an inherited tendency to develop the disease.

FINANCIAL IMPACT

V. R. Gran, K. Panageas and W. Whang of the Columbia University School of Public Health presented a decision analysis of prophylactic treatments in Breast Cancer 1 gene (BRCA1) positive patients. They used a Markov model to determine the cost-effectiveness of prophylactic surgical strategies for patients from high-risk families with the BRCA1 gene. The probabilities used in the analysis were from the study by Easton published in the American Journal of Human Genetics in 1995. Mortality rates were from Surveillance, Epidemiology, and End Results. The costs in the analysis for hospital and ambulatory care were based on Medicare payment data, and managed care and fee-for-service data. The analysis compared careful observation alone with the use of prophylactic oophorectomy with and without bilateral mastectomy. They assumed that bilateral prophylactic oophorectomy would reduce annual risk of ovarian cancer

by 95% and that prophylactic mastectomy would reduce annual risk of breast cancer by 98.8%.

They used a discounted cost of \$13,930 for oophorectomy and \$17,784 for mastectomy and oophorectomy. The cost of observation was \$14,020. Their findings indicated that oophorectomy resulted in 2.6 additional years of life and oophorectomy and mastectomy with 6.5 years.

MEDICAL EFFICACY

Prophylactic Mastectomy

Treatment for breast cancer usually involves some type of surgery. The surgery is often combined with other treatments that include radiation therapy, chemotherapy, hormone therapy, and/or monoclonal antibody therapy, according to the American Cancer Society's "Breast Cancer Fact Book."

Prophylactic mastectomy is another option that women have begun to explore when they are considered high-risk. Prophylactic (preventative) mastectomy involves the removal of one or both breasts when they are healthy. There is no sign of cancer in the patient.

One study reported in the Journal of the National Cancer Institute in November 2001 addressed this procedure as a follow-up to other studies. The study examined the association between bilateral prophylactic mastectomy and breast cancer risk in women who had mutations in BRCA1 and Breast Cancer 2 (BRCA2) genes. Blood samples from 176 of the 214 high-risk women from the previous study were reported to show a decreased risk of subsequent breast cancer by 90%. Twenty-six women with an alteration in BRCA1 or BRCA2 were identified. None of the 26 women had developed breast cancer after a median of 13.4 years. Three of the total of 214 women had developed breast cancer after prophylactic mastectomy. Estimations of the effectiveness of prophylactic mastectomy were performed and predicted that 6 to 9 breast cancers should have developed in the group. The risk reduction was 89.5% with a 95% confidence level. The study conclusion was that prophylactic mastectomy is associated with substantial reduction in the incidence of not only high-risk women based on family history of breast cancer but also BRCA1 or BRCA2 mutation carriers.

Another decision analysis performed by the Center for Outcomes and Policy Research, by Dana-Farber Cancer Institute and Harvard Medical School found that prophylactic mastectomy provides substantial gains in life expectancy and prophylactic oophorectomy more limited gains for young women with BRCA1 or BRCA2 mutations.

Prophylactic Oophorectomy

Prophylactic oophorectomy, surgical removal of healthy ovaries, has been the subject of a number of studies. Researchers at the University of Pennsylvania conducted one recent study. The September 1, 1999 edition of the Journal of the National Cancer Institute contained a report of their findings.

The researchers found a statistically significant reduction in breast cancer risk after bilateral prophylactic oophorectomy. They concluded that bilateral prophylactic oophorectomy is associated with a reduced breast cancer risk for women with a BRCA1 mutation. They considered the reduction of ovarian hormones as the probably mechanism for the reduction.

Prophylactic Colectomy

Some physicians consider prophylactic colectomy for cases where the patient has familia adenomatous polyposis (FAP). Some individuals are considered possible candidates for prophylactic colectomy if they are diagnosed with hereditary nonpolyposis colon cancer (HNPCC). The Medical Advisory Committee of the Cancer BACUP in the United Kingdom made the following statement regarding prophylactic colectomy and ileorectal anastmosis:

This is the most commonly used prophylactic procedure in cases of FAP. There is a need for regular follow-up since it carries a 4% risk of developing cancer for up to 25 years: if the rectal stump is retained, upper gastro-intestinal surveillance is necessary. Subtotal colectomy has been advocated in some cases of HNPCC.

Preventive surgery for FAP is often preferred because of the difficulty of screening for polyps in the patients with colons intact, according to an article "Considering Surgery to Lower Cancer Risk in People with HNPCC" by Miriam Komaromy, M.D.

Coverage in Other States

Information from the National Association of Insurance Commissioners (NAIC), the National Insurance Law Services, and a survey of state insurance departments was reviewed to determine if requirements similar to Senate Bill 619 exist in other states. The information indicates that no other state has enacted legislation similar to Senate Bill 619. Most states have requirements that prevent discrimination based on genetic information. According to information from the NAIC, 46 states address genetic testing for insurance coverage. The laws

generally prohibit genetic information from being used to determine eligibility or insurability and/or to be used as a basis for a preexisting condition limitation.

Virginia legislation addressing the privacy and use of genetic information is found in Section 38.2-508.4. The section defines the terms genetic characteristic, genetic information, and genetic tests. The section prohibits health insurers and HMOs from using genetic information to terminate, restrict, limit, or otherwise apply conditions to coverage or restrict sale of policies or contracts; cancel or refuse to renew coverage; exclude individuals from coverage; impose a waiting period prior to coverage beginning; include a rider to exclude certain benefits and services or establish differentials in premium rates for coverage. The information from screenings and testing is to be considered confidential and is not to be made public in any way.

Current Industry Coverage

The Bureau of Insurance surveyed sixty of the top writers of accident and sickness insurance in Virginia in March 2002 regarding the bills forwarded to the Advisory Commission in 2002. Fifty companies responded to the survey by May 28, 2002. Thirty-six companies completed the survey. Fourteen companies indicated that they currently have little or no business in Virginia that would be subject to Senate Bill 619. Twenty companies indicated that they do not provide the coverage required by the bill. Fifteen companies reported that the coverage is provided by their policies or contracts. One company stated that it was impossible to respond without clarification of the legislation.

Eleven of the companies provided figures for the costs associated with providing the coverage required by the bill. Six companies responded in terms of percentages of policy premium. Those responses were .25% from one company for individual or group standard coverage, and 5% to 10% (four companies) for individual or group standard coverage, and 5% to 10% (four companies) for individual and group coverage on a standard or optional basis. One company indicated that the cost would be .1% for coverage under their standard group policy and .7% for group coverage on an optional basis.

The dollar estimates for individual coverage ranged from .01 to \$11.17 for standard coverage. For optional coverage, the responses were \$7.00 (4 responses), and \$111.68 for individual policies. The estimates for optional group coverage were \$4.20 (4 responses), and \$79.63.

REVIEW CRITERIA

SOCIAL IMPACT

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

The potential utilization of this coverage is significant because of possible future evidence of predisposition to illnesses or disease based on family history or genetic predisposition. The cancer cases most often discussed as requiring use of this coverage at the present time are cancers of the breast, colon, and ovary. The number of Virginians affected annually would be 4,600, 3,200, and 300, respectively.

Those who oppose the bill commented that the broad language of the bill would allow for many treatments and services. A representative of the VAHP supplied information from the European directory of DNA laboratories that cited services for 580 genetic conditions.

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

Coverage for prophylactic surgery has not typically been available. Thirty-six companies completed the Bureau of Insurance survey regarding Senate Bill 619. Fifteen companies reported that the coverage provided by their policies or contract includes the requirements in the bill. Twenty companies indicated that they do not provide the coverage required by the bill and one company stated that it was not possible to respond without clarification of the regulation.

- 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.*

There was public testimony that some people who could benefit from prophylactic surgery go without the surgery because they lack insurance coverage. Emphasis on the need for early detection or action was a theme of the supporters of the bill.

- 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.*

Costs associated with prophylactic surgeries were estimated at a discounted rate in a study by staff at the Columbia University School of Public Health. They used discounted costs of \$13,930 for oophorectomy and \$17,784 for mastectomy and oophorectomy.

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

The cancer cases discussed as most relevant to the bill may affect from 3,000 to 8,100 Virginians each year.

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

The American Cancer Society, two physicians, and 13 consumers provided written comments in support of Senate Bill 619. In addition to a physician from the University of Virginia, a private citizen, and a representative of the Virginia Consumer Action Society for Multiple Sclerosis spoke in favor of the bill at the October 2002 public hearing.

- 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 interest in negotiating 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 a state health planning agency on the social impact of Senate Bill 619.

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.*

The proposed coverage is not expected to effect the cost of treatments over the next five years. However, the language of the bill could require coverage for treatments that have not been developed at this time.

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

The use of the prophylactic surgeries that are the treatments that proponents of the bill discussed is expected to increase but not significantly.

However, VAHP, in its written comments, stated that experimental, controversial, risky or unnecessary services could be covered by the bill. They cited lasik surgery for individuals with a history of vision impairment, and health club memberships for those with a history of cardiovascular disease.

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

The Columbia University School of Public Health decision analysis used costs of \$14,020 for “careful observation” for high-risk patients as compared with \$13,930 for oophorectomy and \$17,784 for mastectomy and oophorectomy.

- d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

The number and types of providers for the prophylactic surgeries discussed by proponents of the bill is not expected to increase significantly over the next five years. However, the language of the bill may cover services not currently provided in the medical field. Five years could allow time for the development of additional areas of expertise as the science of genetics advances.

- 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.*

Eleven companies provided figures for the costs associated with providing the coverage required by this bill. Six companies responded in terms of percentages of policy premium. Those responses were .25% from one company for individual or group standard coverage, and 5% to 10% (four companies) for individual or group standard coverage, and 5% to 10% (four companies) for individual and group coverage on a standard or optional basis. One company indicated that the cost would be .1% for coverage under their standard group policy and 0.7% for group coverage on an optional basis.

The dollar estimates for individual coverage ranged from .01 to \$11.17 for standard coverage. For optional coverage, the responses were \$7.00 (4 responses) and \$111.68 for individual policies. The estimates for optional group coverage were \$4.20 (4 responses) and \$79.63.

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

Proponents of the legislation believe that the bill will not increase the cost of health care because the prophylactic surgeries will prevent the need for surgery or other treatments after conditions have manifested themselves.

Those who oppose the benefit, including the HIAA and VAHP, believe that the potential costs of the benefit are not measurable.

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.*

Proponents of the legislation cited studies by Aurino, Sonika and Pukkala published in the Internal Journal of Cancer in 1999, and Lynch and Lynch in the International Journal of Cancer in 1996, to support the efficacy of prophylactic surgical treatments for breast, ovarian, and colon cancers. Other studies reviewed by the Advisory Commission included the "Efficacy of Bilateral Prophylactic Mastectomy in BRCA1 and BRCA2 Gene Mutation Carriers" by Lynn C. Hartmann et al, "Breast Cancer Risk after Bilateral Prophylactic Oophorectomy in BRCA 1 Mutation Carriers" by Timothy Rebbeck et al, both published in the Journal of the National Cancer Institute.

Proponents made the argument that for some diseases there is no way of detecting the illness until it has progressed to the point that successful treatment is unlikely.

Opponents of the bill, including representatives of Trigon Blue Cross/Blue Shield, expressed concern that treatments would be requested for those who “might” develop an illness or condition and not merely those that will develop the illness or condition.

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 of the bill believe that it addresses a medical need and that it is consistent with the role of health insurance. They point to the results of the previously cited studies on the effectiveness of prophylactic treatments.

Those who oppose the bill, including the VAAHP, HIAA, and Trigon Blue Cross/Blue Shield, noted the open-ended nature of the bill language. They contend that the bill might be interpreted as requiring a wide range of benefits including health club membership. There was concern that many services might be included that are inconsistent with the role of health insurance.

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

Proponents made the argument that prophylactic mastectomy and oophorectomy reduce the risk of breast and ovarian cancer up to 95% in women with BRCA1 or BRCA2 alterations and may lower breast cancer risk in premenopausal women. They noted that prophylactic mastectomy and oophorectomy can also be reassuring to those at risk of hereditary disease. They noted that prophylactic colectomy is the procedure of choice in familial adenomatous polyposis.

Proponents also made the point that because of the lack of definitive tests to identify ovarian cancer in its early stages, prophylactic surgery is the best way to prevent development of the disease. They believe that the preventive treatment is less costly than treatment for “full-blown” disease and, additionally, will alleviate pain and suffering of the patient.

Those who oppose the bill note that it would require coverage for a broad range of services. They believe the cost impact of the bill is difficult to assess because the language in the bill includes family history as well as genetic factors relating to a disease or condition. Trigon Blue Cross/Blue Shield also expressed concerns about the language requiring coverage based on the treating physician’s determination. They believe that use of the term “medically appropriate” could also create difficulty in determining what should be covered.

Opponents of the bill, including Trigon Blue Cross/Blue Shield, VAHP, and the Virginia Chamber of Commerce, noted the effect this proposal could have on access to health care coverage. They believe that the bill could increase the cost of health care coverage and reduce the number of individuals and employers that can afford health care coverage.

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

It is expected that the cost of a mandated offer of coverage would be higher because the cost would rest on only those who select the coverage. 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. Therefore, coverage may not reach some people who need or want it.

RECOMMENDATION

The Advisory Commission voted unanimously (11-0) on November 12, 2002, to recommend against the enactment of Senate Bill 619.

CONCLUSION

The Advisory Commission noted the merits of the proposed bill. However, the Advisory Commission members expressed concerns about the broad language of the bill. Concerns were also discussed regarding the impact of the bill on the cost of health insurance. Additionally, the Advisory Commission members discussed the need for further refinement of the science of genetics, and additional research prior to requiring coverage similar to Senate Bill 619.