REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE FOR OVARIAN CANCER TESTING

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 68

COMMONWEALTH OF VIRGINIA
RICHMOND
2000

COMMONWEALTH OF VIRGINIA

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SENATE

January 10, 2000

To: The Honorable James S. Gilmore, III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §9-298 and §9-299 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 2653, regarding a proposed mandate for ovarian cancer testing.

Respectfully submitted,

Stephen H. Martin
Chairman
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TABLE OF CONTENTS

INTRODUCTION

During the 1999 Session of the General Assembly, the House Committee on Corporations, Insurance and Banking referred House Bill 2653 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission). House Bill 2653 was patroned by Delegate Jay Katzen.

The Advisory Commission held a public hearing on July 28, 1999, in Richmond to receive comments on House Bill 2653. In addition to the patron, three speakers addressed the proposal. Representatives of the American Cancer Society and the Medical Society of Virginia philosophically supported the bill, but requested further dialogue regarding the bill's language. A concerned citizen spoke in favor of the bill. A representative of the Virginia Association of Health Plans (VAHP) spoke in opposition to the bill. Written comments in opposition to the bill were submitted on behalf of the VAHP, Virginia Manufacturers Association (VMA), the Virginia Chamber of Commerce, and Trigon.

The Advisory Commission concluded its review of House Bill 2653 on August 24, 1999.

SUMMARY OF PROPOSED LEGISLATION

The bill requires an accident and sickness insurer, health services plan or health maintenance organization to provide coverage for ovarian cancer screening. The bill applies to individual and group policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, and subscription contracts and health care plans provided by health maintenance organizations. The bill applies to policies, contracts or plans delivered, issued for delivery or renewed on or after July 1, 1999. The bill does not apply to short-term travel, accident only, limited or specified disease policies other than cancer policies, short-term non-renewable policies of not more than six months.

The coverage must be provided to any post-menopausal woman or any woman who is at high-risk of ovarian cancer according to the most recent guidelines of the American Cancer Society. The coverage is to include one CA-125 test or, when available, one LPA test, in a 12-month period according to American Cancer Society guidelines.

The bill defines the term "CA-125 test" as the analysis of a blood sample to determine the presence of the tumor marker CA-125, which may indicate the existence of ovarian cancer cells. The "LPA test" is defined as the analysis of a blood sample to detect elevated levels of lysophosphatidic acid, a substance which stimulates the growth of ovarian cancer cells.

OVARIAN CANCER

Ovarian cancer is the abnormal growth, reproduction and spread of malignant cells located on the ovaries. Its exact cause is unknown. Ovarian cancer is one of the top five leading causes of cancer death in women. It is the leading cause of death from gynecological malignancies. In the case of ovarian cancer, malignant tumors develop quickly (often times involving both ovaries), and shed malignant cells early in the developmental stages of the disease. The cells may spread to the abdominal cavity or the lining of the abdominal cavity. The cells may also grow on the surface of the liver, uterus, bladder, bowel and diaphragm, making these areas susceptible to cancerous growths.

Information provided by the American Cancer Society (ACS) indicated that 25,200 new cases of ovarian cancer will be diagnosed in the United States in 1999. Ovarian cancer accounts for 4% of all cancers in women. There will be nearly 14,500 deaths from ovarian cancer in the U. S. in 1999. About 76 % of ovarian cancer patients survive one year after diagnosis and over 40% survive longer than five years after diagnosis. If diagnosed and treated while the cancer has not spread outside the ovary, the five-year survival rate is 95%. However, only 25% of all ovarian cancers are found at this early stage.

Researchers have discovered several specific factors that increase a woman's likelihood of developing epithelial ovarian cancer. So far, knowledge about risk factors has not been translated into practical ways to prevent most cases of ovarian cancer. According to the ACS, high-risk factors are:

1. Age—most ovarian cancers develop after menopause. On average menopause occurs at age 51. Half of all ovarian cancers are found in women over the age of 65.

2. Maternity—(or parity) on average, women who have their first child after age 30, have a slightly higher risk of developing ovarian cancer than women who have their first child before age 30.

3. Fertility drugs—in some studies researchers have found that prolonged use of the drug clomiphene citrate, especially without achieving pregnancy, may increase a woman's risk of ovarian cancer. Infertility, without the use of fertility drugs, may increase risk. Research clarifying these relationships is underway.

4. Reproductive history—women who started menstruating before age 12, had no children or had their first child after age 30, and/or experienced menopause after age 50 have anincreased the risk of ovarian cancer.

5. Family history of ovarian cancer—ovarian cancer risk is increased among women whose mother, sister, or daughter have, or have had, ovarian cancer, especially if they developed ovarian cancer at a young age. About 7% of ovarian cancers result from an inherited tendency to develop the disease.

6. Breast cancer—the risk of developing ovarian cancer is increased if a woman has, or has had breast cancer. Inherited gene mutations greatly increase risk for breast and ovarian cancer.

7. Diet—the ACS recommends foods from plant sources and limiting intake of high fat foods, especially those from animal sources.

8. Talcum Powder—it has been suggested that talcum powder applied to the genital area may be carcinogenic to the ovaries. In the past, talcum powder was sometimes contaminated with asbestos. Some studies suggest a slight increase in risk of ovarian cancer; other studies find no links.

According to the National Institutes of Health Consensus Development Conference Statement (NIH) dated April, 1994, in the United States, 1 out of 70 women have the chance of developing ovarian cancer at some point in their lives. Older women have a higher incidence of developing the disease than younger women. More than 50% of deaths from ovarian cancer occur in women between 55 and 74 years of age; whereas one-fourth of deaths from ovarian cancer occur in women ages 35 to 54.

It is routinely recommended that all women over the age of eighteen have an annual pelvic and rectal examination since an ovarian mass can occasionally be detected. Another routine examination is the "pap" smear. The pap smear is a test designed to screen for cervical cancer; occasionally, it may find ovarian cancer. The Women's Cancer Center reports that a Pap smear will detect ovarian cancer in only 10% of women with the disease in an on-line article by Dr. Jeffrey L. Stern.

Ovarian cancer may be treated with surgery, chemotherapy or radiation. Treatment depends on a number of individual factors, including the stage of the disease, the woman's age, and her general health. Some women choose to reduce the risk of developing epithelian ovarian cancer by using oral contraceptives, becoming pregnant and breast-feeding, or having surgical procedures such as tubal ligation (tying the fallopian tubes), hysterectomy (removal of the uterus), or prophylactic oophoretomy (removing both ovaries before cancer occurs). Surgery is an option for women with strong family history of ovarian cancer or other valid medical reasons.

CANCER ANTIGEN 125 TESTING (CA-125)

CA-125 is a substance found in the blood of many women with ovarian cancer. Levels of CA-125 in blood are used routinely to check whether a patient's ovarian cancer is responding to medical treatment, is continuing to grow, or is returning after surgery.

The CA-125 serum marker is an antigenic determinant detected by radioimmunoassay (analysis and identification of a substance such as an enzyme or hormone). It is elevated in approximately 80% of epithelian ovarian cancers. Although levels are increased in most advanced ovarian cancers, they are not increased in many early stage ovarian cancers. Benign cells sometimes release CA-125. Benign conditions such as endometriosis (abnormal collections of uterine lining cells inside the ovary), some liver diseases, infections of the fallopian tubes, leiomyomas (benign tumors of muscle cells) of the uterus, benign ovarian cysts, pancreatitis (inflammation of the pancreas), or pregnancy may also result in increased blood levels of CA-125. These conditions could cause CA-125 testing results to reflect as a "false positive" which would lead to unnecessary diagnostic tests or even surgery for many women.

According to an article entitled "Lysophosphatidic Acid as a Potential Biomarker for Ovarian and Other Gynecological Cancers" that appeared in the Journal of the American Medical Association (JAMA) (Vol. 280, pp.719-723, Aug.26, 1998), the CA-125 remains the most widely used biomarker for the detection and management of epithelial ovarian cancer, even though this marker is not highly sensitive and lacks specificity.

LYSOPHOSPHATIDIC ACID (LPA) TESTING

Lysophosphatidic acid (LPA) is a naturally occurring complex of substances that have been shown capable of stimulating cancer cell growth. Although the sensitivity and specificity are encouraging, findings are based on a small series of patients and must be confirmed in a large, longitudinal study.

In Vol. 280, p. 739, of the August 26, 1998 issue of JAMA an article entitled "Searching for a Biomarker for Ovarian Cancer" explains that scientists have presented preliminary data regarding LPA. It is identified as an ovarian cancer-activating factor and suggests that the serum level of this factor correlate with the presence of ovarian cancer. Several issues must be addressed before the LPA can be accepted as a screening test or diagnostic marker for ovarian cancer. The LPA test appears to be too involved for a simple screening test. The test seems unable to significantly distinguish serum level measurements between preoperative, postoperative, and post-chemotherapy patients. Each of these groups of women would be expected to have different tumor loads. Lastly, LPA levels were elevated in women with other gynecologic tumors. Because of this last issue, use of this marker as a screening test for ovarian cancer seems doubtful.

The article further states that elevated plasma levels of lysophosphatidic acid (LPA) are associated with ovarian cancer, and that this test may prove to be more accurate than the CA-125 test. The test is not routinely available and its value needs to be confirmed in larger independent studies. A national repository for blood and tissue samples from ovarian cancer patients is being established to aid in these studies, as well as other recommendations suggested at the NIH.

MEDICAL EFFICACY

To be suitable for screening, a disease must have a significant prevalence and be a significant cause of mortality. There must be a pre-clinical phase that can be detected, and the disease must be responsive to therapy. The screening test itself must have sufficient specificity, sensitivity and positive predictive value to be effective, and it must be cost-effective. In ovarian cancer, if it is assumed that 50 cases per 100,000 population were prevalent for ovarian cancer, a test with 99% specificity and 100% sensitivity would result in only 21 women with a positive screen for having the disease (ie. positive predictive value of 4.8%), according to the National Cancer Institute (NCI). The NCI further states that screening currently available do not attain the above-mentioned level of sensitivity.

The survival rate of women with early stage ovarian cancer is significantly higher than that of women with advanced-stage disease. The larger majority of women with ovarian cancer are diagnosed with the disease in its advanced stages. Early ovarian cancer may have no symptoms or vague symptoms such as gastrointestinal discomfort, pelvic pressure, and pain, or non-specific symptoms. By the time the symptoms are clinically evident, women with ovarian cancer usually have advanced disease.

There is some debate over the effectiveness of the CA-125 blood test in identifying an increased risk of ovarian cancer in women who show no symptoms or women who do not have clearly defined high-risk factors with the disease other than positive family history.

According to the American Cancer Society, the best use of the CA-125 blood test is found in testing women who have already had surgery to remove epithelial ovarian cancer. A positive result can be a warning that the cancer may have recurred.

In a recent study, as reported in REUTERS Health News for April 14, 1999, conducted by Massachusetts General Hospital and St. Bartholomew's Hospital in London, 28 women were identified as having developed ovarian cancer out of a study of 22,000 initially healthy women. The women had undergone CA-125 testing annually for three years beginning age 45. The results suggested that there is a lag of about 1.9 years between the development and the clinical detection of ovarian cancer, and that unless a woman is screened annually rather than every three years, early detection of the disease could be missed.

Dr. Steven Skates, assistant professor of biostatistics at Massachusetts General Hospital, stated in the report that the importance of the timing in administering the CA-125 blood test is critical, because early-stage ovarian cancer is curable, late-stage is not. In the study, if a woman's CA-125 level was elevated, she underwent additional -- screening with pelvic ultrasound and CA-125 tests every three months.

RECOMMENDATIONS FOR SCREENING

All women should have a comprehensive family history taken by a physician knowledgeable in the risks associated with ovarian cancer and should continue to undergo annual rectovaginal pelvic examinations as a part of the routine medical care. A lifetime risk of ovarian cancer in a woman with no affected relatives is 1 in 70, and in a woman with one first-degree relative with ovarian cancer the lifetime risk is 5%. With two or more first-degree relatives, the lifetime risk rises to 7%.

With current knowledge and technology, the benefits of screening a woman who has one or no first-degree relative with ovarian cancer are unproven. Obsession and/or depression regarding the condition, pending results and thoughts of death in women without significant high risks may outweigh any potential benefits in light of the increased possibilities of "false positive" results which would lead to unnecessary diagnostic tests or even surgery for many women. However, participation in clinical screening trials is an appropriate option, and is important in helping to ultimately define the potential benefits and risks of screening.

For patients with a hereditary ovarian cancer syndrome, the lifetime risk of ovarian cancer is about 40%. There is no data that suggests that screening these high-risk women reduces their mortality from ovarian cancer. However, the National Cancer Institute recommends that these women have annual rectovaginal pelvic examinations, along with CA-125 testing and transvaginal ultrasound. When child bearing is completed, or the woman is at least 35 years of age, prophylactic oophorectomy (removal of the ovary (ies) is recommended to reduce the risk).

The National Cancer Institute (NCI) recognizes the following tests in screening for ovarian cancer: the pelvic examination, transvaginal ultrasonography, CA-125 serum marker, pap smear, culdocentesis, and a combination of these tests.

Individual tests alone may not detect ovarian cancer. It may be possible to improve accuracy by combining ultrasound with other screening tests, such as the CA-125. Although it may be recommended that the pap smears be performed less often after three annual smears have been normal, pelvic exams should continue on an annual basis.

At this time, the American Cancer Society does not recommend any blood tests or imaging studies for ovarian cancer screening of women who do not have an increased risk of the disease.

SOCIAL IMPACT

The most recent figures from the Virginia Cancer Registry indicate that in 1995, 489 Virginians died as a result of ovarian cancer. There was a slight decline in 1996 in ovarian cancer deaths, from 489 to 457. This is a conservative account of cancer

deaths in Virginia because all hospitals, outpatient facilities and private pathology labs were not reporting cases to the registry during the time period covered.

Volume 49 of the Cancer Journal for Clinicians reports that 300 women will die in Virginia as a result of ovarian cancer and an estimated 500 new cases will be reported in 1999.

FINANCIAL IMPACT

The average cost of a CA-125 screening test is approximately $45 in New York, according to a representative of the Gilda Radner Familial Ovarian Cancer Registry. Local laboratories in the Central Virginia area quote the range of costs of a CA-125 test from $92.50 (outpatient) to $135.80 (inpatient).

An article entitled, "The Genetics of Ovarian Cancer: An Assessment of Current Screening Protocols and Recommendations for Counseling Families at Risk" that appeared in Clin Obstet Gynecol 1996 Dec; 39 (4): 860-72 states that given that there are more than 43 million women in the United States older than 45 years of age and that the average cost of a pelvic sonogram is $275 (and $45 for a CA-125 screening). The screening of this population is estimated to increase health care costs by $14 billion per year.

CURRENT INDUSTRY PRACTICES

The Bureau of Insurance (Bureau), in its capacity as staff to the Advisory Commission, surveyed fifty of the top writers of accident and sickness insurance in Virginia regarding House Bill 2653. Twenty-nine (29) companies responded. Four (4) companies indicated that they write no applicable health insurance policies in Virginia, or provide no coverage in this area and could not provide the information requested. Of the twenty-five (25) respondents that completed the survey, nine (9) companies indicated that they currently provide coverage for certain ovarian cancer testing as a part of their standard benefit package. One (1) company that writes limited contracts that are subject to the bill also covers ovarian cancer testing. Nine (9) companies do not include the coverage. Five (5) companies include the coverage in individual contracts, but not group contracts. One (1) company does not include coverage in its contract, but covers testing if ordered by a physician.

Respondents to the Bureau survey provided cost figures between $0.26 and $2.08 per month per standard individual policy and between $0.05 and $4.16 per month per standard group policy to provide the coverage specified in House Bill 2653. Insurers providing coverage on an optional basis provided cost figures ranging from $.06 to $13.80 per month per optional individual policy and between $1.05 and $4.64 per month per optional group policy.

SIMILAR LEGISLATION IN OTHER STATES

Information from the National Insurance Law Service and individual states indicates that along with Virginia, California, New York and Delaware have introduced legislation requiring screening and diagnostic testing for ovarian cancer testing. In New York, four different bills have been referred to committee (AB 1770, AB 3513, SB 5007, SB 872). Assembly Bill 3513 has passed the Assembly.

In California, Senate Bill 362 is in committee. The Delaware legislation requires benefits for outpatient services to covered persons residing in the state. The benefit is for CA-125 monitoring of ovarian cancer subsequent to treatment.

The Georgia House of Representatives has created the House Ovarian Cancer Study Committee to study the conditions, needs, issues and problems related to ovarian cancer and recommend or propose legislation which the committee deems necessary or appropriate. The report will be made on or before December 1, 2000.

The National Association of Insurance Commissioners indicates that of the fifty states, twenty states specifically require coverage for annual pelvic exams or annual pap smears.

REVIEW CRITERIA:

SOCIAL IMPACT

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

The ACS estimates that approximately 25,200 new cases of ovarian cancer will be diagnosed in the United States during 1999. The ACS also estimates that there will be about 14,500 deaths from ovarian cancer in the United States. Five hundred new ovarian cases will be reported in Virginia according to the ACS's Cancer Journal for Clinicians cancer statistics for 1999. Approximately 300 deaths will be reported in Virginia as a result of ovarian cancer in 1999.

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

In a 1999 State Corporation Commission Bureau of Insurance survey of the 50 top writers of accident and sickness insurance in Virginia, twenty-five (25) companies currently writing applicable business in Virginia responded. Of that number, ten (40%) already provide the coverage required by House Bill 2653.

One company did not include the coverage in its contract, but covers the testing if ordered by a physician.

Most health insurance policies include coverage for an annual pelvic and rectal examination that may occasionally detect an ovarian mass. The pap smear screens women for cervical cancer.

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.

The Virginia Association of Health Plans (VAHP), in written comments states that coverage for CA-125 testing appears to be available in the marketplace. Several VAHP member plans currently include CA-125 testing as a part of their benefits package. If a test is considered medically necessary by a physician, then it is covered by basic insurance plans, but routine screenings are not deemed medically necessary.

According to the most recent statistics provided by the Virginia Cancer Registry, 1,919 cases of ovarian cancer were reported between 1990 and 1994. In 1995, 489 Virginians died as a result of ovarian cancer. There was a slight decline in 1996 in ovarian cancer deaths, from 489 to 457. This is a conservative account of cancer deaths in Virginia because all hospitals, outpatient facilities and private pathology labs were not reporting cases to the registry during the period covered.

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.

According to a representative of the Gilda Radner Familial Ovarian Cancer Registry, the average cost of a CA-125 test is approximately $45.00 in New York. Local laboratories in the Central Virginia area quote the range of costs of a CA-125 test from $92.50 (outpatient) to $135.80 (inpatient). However, there is a potential for abnormal screening test results that may lead to more diagnostic testing or surgery, and this circumstance may cause significant anxiety.

Insurers contend that coverage is generally available if medically necessary.

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

The ACS estimates that approximately 25,200 new cases of ovarian cancer will be diagnosed in the United States during 1999. The ACS also estimates that there will be about 14,500 deaths from ovarian cancer in the United States. Five hundred new ovarian cases will be reported in Virginia according to the ACS's Cancer Journal for Clinicians, cancer statistics for 1999. Approximately 300 deaths will be reported as a result of ovarian cancer in 1999.

More than 50% of deaths from ovarian cancer occur in women between 55 and 74 years of age. Twenty-five percent of deaths from ovarian cancer occur in women aged 35 to 54.

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

Experts do agree that early detection is key, however, The National Institutes of Health "Consensus Conference Statement on Ovarian Cancer" as published in JAMA 273 (6): 491-497, 1995 recommended that women carefully review their family history and have an annual pelvic examination. The pelvic examination, including a palpation of the adnaxae, is recommended for all women over age 18 by several medical associations and professional health organizations.

The American Cancer Society does not advocate use of the CA-125 as a mass screening device for ovarian cancer. In written comments, the ACS stated that a patient should consult with her physician to determine the need for, and type of ovarian cancer screening. If the health care provider determines that the CA-125 test is medically necessary, the screening should be covered.

The NCI has found there is insufficient evidence to establish screening for ovarian cancer with serum markers (such as CA-125 levels) that would result in a decrease in mortality from ovarian cancer. The CA-125 blood test does not have a sufficiently high sensitivity to be recommended for routine screening of ovarian cancer. The blood test misses approximately half of all early tumors.

Opponents contend that more research is needed. Evidence is limited on whether tumor markers become elevated early enough in the early stages of the disease to provide adequate accurate results. It may be possible to improve the specificity of CA-125 screening if combined with other screening tests. The NCI plans to test the utility of transvaginal ultrasound and CA-125 measurement in reducing the mortality from ovarian cancer.

The lysophosphatidic acid (LPA) test may prove to be more accurate than the CA-125 test. The test is still not routinely available and its value needs to be confirmed in larger independent studies. A national repository for blood and

tissue samples from ovarian cancer patients is being established to aid in these studies, as well as other recommendations suggested at the NIH.

The Virginia Manufacturers Association, in written comments states that if the chief objective of any insurance is protection against financial catastrophe, then mandating insurance reimbursement for relatively inexpensive screening or tests does not serve that objective. The argument is that coverage may increase utilization of these tests, for patients may be less likely to require education about the merit of a test if a third party (insurance company) appears to be paying for it, but the cost will be reflected in increased premiums.

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 interests 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.

The Advisory Commission is not aware of any information or relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of this mandated benefit during this review.

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.

No information was provided that would suggest that enactment of House Bill 2653 would either increase or decrease the cost of screening tests.

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

Opponents raised concerns that the bill contained language that would endorse one test (the LPA) not yet available in the United States nor approved by the Food and Drug Administration. A second screening test (the CA-125) is not endorsed by the National Cancer Institute, and is considered preliminary and inconclusive.

The ACS does not advocate use of the CA-125 as a mass screening device. The sensitivity and specificity of available screening tests for ovarian cancer in asymptomatic women are uncertain and require further study. This organization in written comments stated that it does support use of the CA-125 when recommended for women at risk for ovarian cancer, and that insurance should cover the testing if it is medically necessary.

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 alternative to the mandated screening is for the cancer to advance. The key is recognizing the risk factors that increase a woman's likelihood of developing ovarian cancer versus mass screening. Sixty-six percent of women with ovarian cancer have advanced disease at the time of diagnoses. Effective treatment at the advanced stage would be considerably more expensive than the cost of screening tests. The limited choices would be surgery, chemotherapy, radiation, or clinical trials.

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 likely that the proposed mandate would not affect the number and types of providers over the next five years.

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.

Respondents to the State Corporation Commission Bureau of Insurance survey provided cost figures between $0.26 and $2.08 per month per standard individual policy and between $0.05 and $4.16 per month per standard group policy to provide the coverage specified in House Bill 2653. Insurers providing coverage on an optional basis provided cost figures ranging from $.06 to $13.80 per month per optional individual policy and between $1.05 and $4.64 per month per optional group policy.

An increase in the administrative expenses of insurance companies and the premium and administrative expenses for policyholders is anticipated because of the expenses associated with such things as policy redesign, form filings, claims processing systems and marketing, and other administrative requirements.

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

An article entitled, "The Genetics of Ovarian Cancer: An Assessment of Current Screening Protocols and Recommendations for Counseling Families at Risk" that appeared in Clin Obstet Gynecol 1996 Dec; 39 (4): 860-72 states that given that there are more than 43 million women in the United States older than 45 years of age and that the average cost of a pelvic sonogram is $275 (and $45 for a CA-125 screening), the screening of this population is estimated to increase health care costs by $14 billion per year.

HIAA, the VMA and the Virginia Chamber of Commerce are opposed to additional mandated benefits because of the effect of incremental premium increases, and the potential to reduce the number of individuals that have the benefits of health insurance.

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 Institutes of Health "Consensus Conference Statement on Ovarian Cancer" as published in JAMA 273 (6): 491-497, 1995 states that there is no evidence available yet that the current screening modalities of CA-125 and transvaginal ultrasound can effectively be used for widespread screening to reduce mortality from ovarian cancer nor that their use will result in decreased rather than increased morbidity and mortality. Routine screening has resulted in unnecessary surgery with its potential risks. It is important to identify and validate effective screening modalities. Currently available technology for screening should be used in the context of clinical trials to determine the efficacy of these modaliites and their impact on ovarian cancer. Research should be continued to identify additional markers such as LPA and imaging techniques that will be useful.

According to the ACS, the main value of the CA-125 screening test is for women who have already had surgery to remove an ovarian cancer. In these women, the CA-125 tests are done periodically to assess response to therapy and to follow patients after therapy is complete. A positive result can be a valuable warning sign that the cancer may have recurred.

If this test were to be used for ovarian cancer screening, it is believed by the ACS that its high rate of false-positive results would lead to unnecessary diagnostic tests or even surgery for many women.

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.

House Bill 2653 addresses the medical need of screening women at risk for ovarian cancer. The benefit is consistent with the role of health insurance. Although various tests can detect occasional asymptomatic tumors, there is currently no evidence that routine screening will improve overall health outcomes.

Opponents believe that mandating a test that has not been approved for use in the general population (LPA), or a test that is not recommended for mass screening (CA-125) is not in the public's or purchasers' best interest.

The Virginia Manufacturers Association stated in written comments that relatively inexpensive screening tests for conditions other than those incidents that are likely to result in imminent death or mental retardation do not serve what they believe to be the primary objective of any insurance.

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

The National Institutes of Health Consensus Conference on Ovarian Cancer as published in JAMA 273 (6): 491-497, 1995 states that there is no evidence available yet that the current screening modalities of CA-125 and transvaginal ultrasound can be effectively used for widespread screening to

reduce mortality from ovarian cancer nor that their use will result in decreased rather than increased morbidity and mortality.

Opponents believe that the continual mandating of additional benefits is not good public policy and can have the ultimate effect of making health care too costly for individuals and small businesses least able to afford it.

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 voted (6-No, 1-Yes) on August 24, 1999 to recommend that House Bill 2653 not be enacted.

CONCLUSION

The Advisory Commission concluded that based on the information received during this review, some coverage for ovarian cancer screening is available. A mandate for CA-125 testing is not believed to be warranted at this time, nor is a mandate for LPA screening.

999028316

HOUSE BILL NO. 2653

Offered January 21, 1999

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 38.2-3418.8, relating to coverage for certain ovarian cancer testing.

Patrons—Katzen, Black, Davis and Drake; Senators: Couric and Potts

Referred to Committee on Corporations, Insurance and Banking

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 38.2-3418.8 as follows:

§ 38.2-3418.8. Coverage for certain test for ovarian cancer.

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 health care plan for health care services shall provide coverage to (i) any post-menopausal woman or (ii) any woman who is at high risk of ovarian cancer, according to the most recently published guidelines of the American Cancer Society, for one CA 125 test or, when available, one LPA test, in a twelve-month period, all in accordance with American Cancer Society guidelines under any such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1999.

B. For the purpose of this section:

"CA 125 test" means the analysis of a blood sample to determine the presence of the tumor marker, CA 125, which may indicate the existence of ovarian cancer cells.

"LPA test" means the analysis of a blood sample to detect elevated levels of lysophosphatidic acid (LPA), a substance which stimulates the growth of ovarian cancer cells.

C. The provisions of this section shall not apply to (i) short-term travel, accident only, limited or specified disease policies other than cancer policies, (ii) short-term nonrenewable policies of not more than six months' duration, or (iii) policies of 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, 38.2-200, 38.2-203, 38.2-210 through 38.2-213, 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.) of this title, 38.2-1057, 38.2-1306.2 through 38.2-1309, Articles 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, 38.2-3407.9, 38.2-3407.10, 38.2-3407.11, 38.2-3407.12, 38.2-3411.2, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.7~~ *38.2-3418.8*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3542, 38.2-3543.2, Chapter 53 (§ 38.2-5300 et seq.) and Chapter 58 (§ 38.2-5800 et seq.) 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.