REPORT OF THE SPECIAL ADVISORY COMMISSION ON MANDATED HEALTH INSURANCE BENEFITS

MANDATED COVERAGE OF ANNUAL PROSTATE-SPECIFIC ANTIGEN TEST

(SENATE BILL 1003, 1997)

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 13

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HOUSE OF DELEGATES
RICHMOND

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December 12, 1997

To: The Honorable George Allen
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 (Advisory Commission) to assess the social and financial impact and the medical efficacy of Senate Bill 1003, regarding mandatory coverage of annual prostate-specific antigen testing.

This report is respectfully submitted on behalf of the remaining members of the Advisory Commission.

Member, Virginia House of Delegates
Special Advisory Commission on
Mandated Health Insurance Benefits

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INTRODUCTION

The 1997 Senate Committee on Commerce and Labor referred Senate Bill 1003 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to be reviewed prior to the 1998 Session of the General Assembly. Senate Bill 1003 is patroned by Senator Kenneth W. Stolle.

The Advisory Commission held a public hearing to receive comments on Senate Bill 1003 on August 27, 1997, in Richmond. In addition to the bill's chief patron, two oncologists, a representative from the American Foundation for Urologic Disease (AFUD), and four prostate cancer survivors spoke in support of the bill. Written comments supporting Senate Bill 1003 were received from the AFUD, the American Cancer Society (ACS), the American Urological Association (AUA), the American Prostate Society (APS), and five interested parties. Representatives from the Virginia Association of Health Maintenance Organizations (VAHMO) and the Virginia Manufacturers Association (VMA) spoke in opposition to the bill. Written comments opposing the bill were received from the VAHMO, VMA, Trigon Blue Cross Blue Shield (Trigon), and the Virginia Chamber of Commerce (VCC).

The Advisory Commission concluded its review of Senate Bill 1003 on September 17, 1997.

SUMMARY OF PROPOSED LEGISLATION

Senate Bill 1003, as introduced, would amend the accident and sickness chapter of Title 38.2 of the Code of Virginia by adding § 38.2-3418.3. Senate Bill 1003 requires 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 (HMO) providing a health care plan for health care services to provide coverage for annual prostate-specific antigen (PSA) testing under such policy, contract or plan delivered, issued for delivery or renewed. The bill defines "PSA testing" as the analysis of a blood sample to determine the level of prostate-specific antigens.

At the September 17, 1997 meeting of the Advisory Commission, the ACS submitted two amendments to Senate Bill 1003. The first amendment expands coverage to include Digital Rectal Examinations (DRE) in conjunction with the PSA test. The second amendment includes language that establishes the threshold age at which males would begin accessing these benefits according to the guidelines established by the ACS. The ACS recommends that men 50 years of age or older and men 40 years of age or older who are at high-risk receive an annual DRE and PSA test.

Senator Stolle agreed to the ACS's amendments and added a third amendment to include language excluding "policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans." Draft legislation incorporating Senator Stolle's amendment was not available during the Advisory Commission's review of Senate Bill 1003. The Advisory Commission also considered a technical amendment that would remove the term "annual" in the bill and replace it with the phrase "one test in a 12-month period."

PROSTATE CANCER

Prostate cancer is a relatively slow growth of abnormal cells in the prostate. Most men die with prostate cancer rather than from it. Early-stage prostate cancer often does not cause outward symptoms. However, when symptoms do occur, they may include: frequent need to urinate (especially at night), difficulty starting or stopping urination, weak or interrupted flow of urine, painful urination or ejaculation, blood in urine or semen, and pain or stiffness in the lower back, hips or upper thighs.

According to the National Cancer Institute (NCI), prostate cancer is the most frequently diagnosed cancer in American men, accounting for about 36% of all cancer cases. The ACS reports that 4,900 men in Virginia will be diagnosed with prostate cancer in 1997. The American Institute for Cancer Research reports that prostate cancer rates increase sharply with age, and that over 80% of cases are diagnosed in men age 65 and older. The ACS states that the five-year survival rate for patients whose tumors are diagnosed while still localized is 99%. The ACS also reports that 63% of men diagnosed with prostate cancer survive ten years and 51% survive 15 years.

Information provided by the ACS indicated that between 1987 and 1992 the incidence rate of prostate cancer increased 84%. Between 1992 and 1993, the incidence rate declined 11%. The ACS attributed the rapid increase in the late 1980s and early 1990s, and the decline in the early 1990s, to cancer screening tests such as the PSA test. The ACS explained that when a screening test is rapidly and widely adopted by the general population, the incidence rate for the disease under scrutiny will increase at first and then experience a decline.

According to the NCI, there are three screening exams for prostate cancer: the digital rectal examination (DRE), the transrectal ultrasound, and the PSA test. The DRE is often the first test used to screen for prostate cancer.

During a DRE, the doctor puts a gloved finger into the rectum to feel for hard or lumpy areas in the prostate. During a transrectal ultrasound test, sound

waves, sent out by a probe in the rectum, bounce off the prostate, and a computer uses the echoes to create a sonogram. The PSA test is a blood test used to measure the difference between normal and abnormal outputs of PSA in the prostate gland.

PROSTATE-SPECIFIC ANTIGEN TESTING

The APS noted that both normal prostate cells and cancerous prostate cells produce the same kind of PSA. Under normal circumstances, PSA is not found in significant amounts in a healthy man's blood. However, prostate cancer cells produce about ten times the amount of PSA as normal prostate cells. Men with a PSA level higher than 4.0 nanogram/milliliter (ng/ml) should be evaluated further to determine if cancer is present. The AFUD reported that there are many factors that can cause PSA to rise, but PSA itself is harmless. Causes of an elevated PSA include: benign prostatic hyperplasia or BPH (non-cancerous enlargement of the prostate), prostate infection, prostate biopsy, and prostate cancer. The yearly PSA blood test is used, in conjunction with the DRE, to find men who may have prostate cancer and who need further testing. The AFUD explained that prostate cancer is not actually diagnosed by PSA tests or DRE. PSA tests and DRE help to identify men at higher risk for prostate cancer. Once these men are identified, a biopsy of the prostate is conducted. Often four to six biopsies are taken at a time. One prostate cancer patient stated, in written comments, that discovering the disease while it is still contained within the prostate is the immediate goal of supporters of Senate Bill 1003.

Many men do not take PSA tests for fear of being diagnosed with prostate cancer. A prostate cancer patient explained that one argument against taking the PSA test is that the cure for prostate cancer can be worse than the disease. He explained that many men are told that the diagnosis of prostate cancer may lead to a treatment that has possible negative side effects including death, impotence, and incontinence. The prostate cancer patient explained that death is rare, and the incidence of impotence has declined significantly. After prostate surgery, short-term incontinence is a given; however, permanent incontinence is rare.

The AFUD noted that before deciding whether to have a PSA test, one should decide whether they are willing to undergo treatment for prostate cancer. Since physicians are not in full agreement on the value of the test, the decision should be the personal decision of the patient.

MEDICAL EFFICACY

There is some debate over the effectiveness of the PSA test in identifying an increased risk of prostate cancer. The ACS, the AUA, and the American College of Radiology recommend that men begin undergoing an annual DRE at age 40 as part of their regular physical examination. The ACS also recommends a DRE along with a PSA test annually for men 50 years and older. Men in high-risk groups, such as African-Americans, or those with a strong family history of prostate cancer, should begin undergoing screening at a younger age.

A 1995 study on prostate cancer conducted by the *Hypermedia PDQ Project* reported that of the 1,726 men (between 55 and 76 years of age) participating in the study, 67 incidents of cancer were found. Two incidents were found by transrectal ultrasonography and three by DRE alone. The remaining 62 cases were found through the use of the PSA test. The study found that the PSA test was the most important single predictor of prostate cancer, followed by DRE. The study concluded that the combination of the PSA test and DRE should remain the standard for detecting an increased risk of prostate cancer.

According to the APS, doctors can detect eight of ten prostate cancers with PSA testing before they spread beyond the prostate. Nine of ten prostate cancers caught before they spread can be cured, and the lives of those men saved. Prostate cancer found after it breaks through the wall of the prostate is beyond a cure. At that point, the cancer can only be slowed and the pain controlled.

The June, 1997 report of the Agency for Health Care Policy and Research (AHCPR) states that available evidence does not yet support the ACS's recommendation. In a recent study, the AHCPR found that the use of the PSA test to screen for prostate cancer resulted in 15% of men in their 50s and 40% of men in their 70s requiring further invasive evaluation with biopsy following suspicious PSA results. The study found a net benefit of 6 days to 2.5 weeks of prolonged life per man screened if the cancer was localized and if the ensuing radical prostatectomy was successful. The researchers concluded that the lack of direct evidence showing a net benefit of screening for prostate cancer mandates more clinician-patient discussion for this procedure than for many other routine tests.

In a March 16, 1997 article in the *Richmond Times-Dispatch (RTD,)* entitled "Prostate Testing Is Opposed," The American College of Physicians (ACP), an organization of 100,000 internal medicine specialists, concluded that there is no evidence that patients benefit from routine screening for prostate cancer and recommended against regular testing for all men. The ACP explained that because of uncertainties in the reliability of the tests, and the substantial risks of aggressive early treatment, the organization decided that

screening should be approached as an "individual decision" of each patient in consultation with their physician. The RTD article notes that both patients and physicians question whether the risks of early aggressive treatments outweigh the threat of prostate cancer. Prostate cancer often develops so slowly that patients die of some other cause before the cancer becomes severe.

The NCI contends that, at this time, there is insufficient evidence to establish whether a decrease in mortality from prostate cancer occurs with screening by digital rectal examination, transrectal ultrasound, or serum markers including PSA. The NCI notes that, while both PSA testing and transrectal ultrasound enhance detection when added to DRE screening, they are known to have relatively high "false positive" rates. PSA tests and DREs may also identify a greater number of medically insignificant tumors, leading to unnecessary emotional trauma for a patient. The relatively high rate of "false positive" results means that PSA screening might lead to treatment that is not of proven benefit and that could result in morbidity (including impotence and incontinence) and mortality.

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 Senate Bill 1003. Thirty-five companies responded by the May 2, 1997 deadline. Five companies indicated that they write little or no applicable health insurance policies in Virginia and could not provide the information requested. Of the 30 respondents that completed the survey, 15 indicated that they currently provide coverage for an annual PSA test as part of their standard benefit package to both individual policyholders and group certificate holders. Three companies that responded that coverage is provided under their standard benefit packages indicated that they cover the test if it is considered medically necessary.

Fifteen respondents indicated that they do not provide the coverage for an annual PSA test as part of their standard benefit package. One company indicated that PSA testing is only covered if it is diagnostic. Another company stated that the PSA test is not considered an acceptable guideline. Two companies responded that they provide optional coverage for an annual PSA test to their individual policyholders.

FINANCIAL IMPACT

Respondents to the Bureau survey provided cost figures of between less than $0.01 and $5.00 per month per standard individual policy and between $0.05 and $5.00 per month per standard group certificate to provide the coverage specified in Senate Bill 1003. Insurers providing coverage on an

optional basis provided cost figures ranging from $0.04 to $10.00 per month for both individual policies and group certificates.

Information provided by the Medical College of Virginia's (MCV) General Pathology Services indicated that the outpatient laboratory cost for the PSA test is $70 per screening. This figure does not include costs associated with the general office visit. The inpatient laboratory cost for the PSA test is $60. This figure does not include the cost of hospitalization.

Lab Corp., which handles a large percentage of the PSA tests in the Richmond area, reported that the laboratory cost for the test is $81 per screening. This figure does not include the cost of the visit by the patient to his physician.

When compared to screening for breast cancer, proponents indicated that breast cancer screening is 3.7 to 5.2 times more costly than screening for prostate cancer. Proponents also submitted comments noting that treatment for prostate cancer that goes undetected can range from $20,000 to $25,000 depending upon the stage of the cancer.

MEDICAID AND MEDICARE PROGRAMS

Neither the Medicaid Program nor the Medicare Program provide coverage for the PSA test as a screening tool. The Department of Medical Assistance Services indicated that the Medicaid program covers PSA tests when they are medically necessary; that is, when there is a medical indication that a test is appropriate. Medicaid does not cover routine screenings for any recipients over the age of 21.

Currently, Medicare provides coverage for the PSA test only when the patient has signs and/or symptoms of a disorder, or the patient has a previous diagnosis that justifies the tests. These signs, symptoms or diagnoses must be clearly supported by the patient's medical history.

In July, the U.S. Congress passed the Balanced Budget Act of 1997 (Act). A representative of the Health Care Financing Administration's regional office notified staff by telephone that, effective January 1, 2000, the Medicare program will provide coverage for annual prostate cancer screening for men age 50 and older. The Act requires coverage for (i) an annual DRE, (ii) an annual PSA test, and (iii) effective January 1, 2002, any other procedure for prostate cancer screening that the Secretary of Health and Human Services deems appropriate.

SIMILAR LEGISLATION IN OTHER STATES

According to information provided by the National Association of Insurance Commissioners and the National Insurance Law Service, ten states mandated coverage for an annual PSA test during the Advisory Commission's review. Of those states, five states' statutes require coverage for the PSA test for all men 50 years of age or older, and for men at least 40 years of age who are in high-risk categories or have a family history of prostate cancer.

REVIEW CRITERIA

SOCIAL IMPACT

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

The NCI reports that prostate cancer is the most frequently diagnosed cancer in American men, accounting for about 36% of all cancer cases. Prostate cancer is the second leading cause of cancer death for men. The ACS notes that 4,900 men in Virginia will be diagnosed with prostate cancer in 1997. The ACS also reports that between 1987 and 1992, the incidence rate of prostate cancer increased by 84%, and that between 1992 and 1993, the incidence rate declined 11%. The ACS attributes the rapid increase in the late 1980s and early 1990s, and the decline in the early 1990s, to cancer screening tests such as the PSA test.

A representative from the AFUD stated in oral comments that one man will be diagnosed with prostate cancer every 3 minutes, and one man will die from the disease every 13 minutes.

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

Of the 30 respondents that completed the Bureau's insurer survey, 15 indicated that they provide the coverage required by Senate Bill 1003 to their Virginia policyholders as part of their standard benefit package. One insurer responding to the survey indicated that PSA testing is only covered if it is diagnostic. Another company responded that the PSA test is not considered an acceptable guideline for diagnosing prostate cancer.

VAHMO cited a survey of its members that found that 14 of the 16 respondents provide coverage for PSA testing. The VAHMO survey also found that, in most cases, such testing is within the discretion of the patient's

physician. Trigon indicated that while it does not cover annual PSA screening, its HMOs do cover annual PSA testing.

One proponent contended that HMOs generally oppose mandates on the principle that less regulation is better for the health insurance market. The proponent further contended that by not endorsing Senate Bill 1003, men's lives are being sacrificed for the economies of health insurance.

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.*

Opponents contended that coverage is generally available. Opponents questioned the necessity of providing coverage for PSA testing for all men of a certain age, whether signs or symptons of prostate cancer are present or whether the men are in high-risk categories. Trigon contended that coverage for PSA testing is available for patients with signs and symptoms of disease or who are undergoing various therapeutic interventions or biopsy of the prostatic gland. VMA noted in written comments that mandates, such as Senate Bill 1003, affect only about one-third of the population.

Proponents argued that coverage for PSA testing is not generally available until the disease has reached an advanced stage. One proponent noted that prostate cancers detected by PSA screening are 67% to 88% curable, when diagnosed before spreading beyond the prostate. The AUA stated in written comments that the PSA tests should be a tool for every urologist to use because prostate cancer is a major killer of adult men.

One prostate cancer patient noted that the PSA test is beneficial because it provides for early detection that allows the cancer to be discovered while still in the prostate. He further stated that the issue is not soley to extend the life expectancy of a man. The issue is that PSA testing can save men from a horrible death from cancer. He noted that PSA testing gives the patient a chance at a normal life expectancy with an acceptable quality of life.

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 information provided by the Medical College of Virginia's (MCV) General Pathology Services, the outpatient laboratory cost for the PSA test is $70 per screening. This figure does not include costs associated with the general office visit. The inpatient laboratory cost for the PSA test is $60. This

figure does not include the cost of hospitalization. Lab Corp., which handles a large percentage of the PSA tests in the Richmond area, reported that the laboratory cost for the test is $81 per screening. This figure does not include the cost of the visit by the patient to his physician.

Proponents submitted a cost figure of $34.36 per screening for a PSA test combined with a DRE. This figure does not include the cost of the office visit. Proponents also submitted comments noting that treatment for prostate cancer that goes undetected can range from $20,000 to $25,000 depending upon the stage of the cancer.

Opponents contended that coverage for annual PSA testing is not necessary for all men. Coverage is available for those men who exhibit symptoms associated with problems with the prostate. VMA contends that enactment of mandates, such as Senate Bill 1003, causes financial hardship for those needing health insurance the most. VMA further contends that mandates make commercial insurance too expensive, and some employers are forced to forgo health insurance.

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

The ACS noted that 4,900 men in Virginia will be diagnosed with prostate cancer in 1997. The ACS also reported that between 1987 and 1992, the incidence rate of prostate cancer increased by 84% and that between 1992 and 1993, the incidence rate declined 11%. The ACS attributed the rapid increase in the late 1980s and early 1990s, and the decline in the early 1990s, to cancer screening tests such as the PSA test. The ACS explained that when a screening test is rapidly and widely adopted by the general population, the incidence rate for the disease under scrutiny will increase at first and then experience a decline.

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

Two oncologists spoke in support of Senate Bill 1003. Written comments supporting the bill were received from the AUA, AFUD, and APS. The AUA noted in written comments that the availabiltiy of PSA testing has given physicians a valuable tool for early detection and diagnosis for prostate cancer and will save lives of an untold number of men.

Some providers do not agree that an annual PSA test is an effective method of detecting prostate cancer. The ACP, an organization of 100,000 internal medicine specialists, concluded that there is no evidence that patients

benefit from routine screening for prostate cancer and recommend against regular testing for all men. The ACP further explained that because of uncertainties in the reliability of the tests, and the substantial risks of aggressive early treatment, screening should be approached as an "individual decision" of each patient in consultation with their physician.

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

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

h. *Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

No 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 was presented 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 by either proponents or opponents that would suggest that enactment of Senate Bill 1003 would either increase or decrease the cost of PSA testing.

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

Proponents anticipate that the proposed mandate will increase the appropriate use of the PSA test. Men who are in a high-risk category or who are fearful of developing prostate cancer will obtain PSA testing. One prostate cancer survivor submitted comments noting that mandating the PSA test, to be used in conjuction with the DRE, can save an untold number of men's lives from a horrible death from prostate cancer.

Opponents expressed concern that Senate Bill 1003 will increase the inappropriate use of a screening tool that is not considered an acceptable

guideline for diagnosing prostate cancer. The NCI notes that, while both PSA testing and transrectal ultrasound enhance detection when used in conjuction with DRE screening, they are known to have relatively high "false positive" rates. PSA tests and DREs may also identify a greater number of medically insignificant tumors, leading to unnecessary emotional trauma for a patient. The relatively high rate of "false positive" results means that PSA screening might lead to treatment that is not of proven benefit and that could result in morbidity (including impotence and incontinence) and mortality. The NCI concluded that it cannot be determined from earlier studies whether PSA screening will reduce prostate cancer mortality.

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

According to information provided by the Medical College of Virginia's (MCV) General Pathology Services, the outpatient laboratory cost for the PSA test is $70 per screening. This figure does not include costs associated with the general office visit. The inpatient laboratory cost for the PSA test is $60. This figure does not include the cost of hospitalization. Lab Corp., which handles a large percentage of the PSA tests in the Richmond area, reports that the laboratory cost for the test is $81 per screening. This figure does not include the cost of the visit by the patient to his physician.

One proponent noted in written comments that when including all screenings and tests, the cost of finding each case of prosate cancer is approximately $2,000, while the average cost of a prostatectomy is approximately $20,000 to $25,000 depending upon the stage of the cancer. An article provided by a prostate cancer victim, entitled "An Economic Rationale for Prostate Cancer Screening," reported that a study conducted by the University of Maryland School of Medicine in Baltimore suggests that prostate cancer screening is at least equally cost-effective and possibly more cost-effective than breast cancer screening.

A prostate cancer survivor noted in written comments that had he received a PSA test earlier, his HMO and Medicare would not have had to pay several thousands of dollars for intensive radiation treatments. He contended that had his cancer been diagnosed earlier, he could have undergone less expensive and less intensive 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.*

The number and type of providers of the mandated service are not expected to increase over the next five years as a result of this bill.

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.*

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

Respondents to the Bureau survey provided cost figures of between less than $0.01 and $5.00 per month per standard individual policy and between $0.05 and $5.00 per month per standard group certificate to provide the coverage specified in Senate Bill 1003. Insurers providing coverage on an optional basis provided cost figures ranging from $0.04 to $10.00 per month for both individual policies and group certificates.

Insurers contended that mandates serve only to drive up the cost of health insurance making coverage unaffordable for those who need it most. Trigon stated in written comments that it opposes Senate Bill 1003 because it is most appropriate for the marketplace to decide what benefits should be provided.

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

The total cost of health care is not expected to be significantly affected.

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.*

Opponents questioned the medical efficacy of annual PSA testing. Several insurers noted that currently PSA testing is not recognized by the American Medical Association as the preferred diagnostic tool for prostate cancer. The VCC opposed mandating coverage for an annual PSA test because rapidly advancing science and technology might soon present a better test which would require a change in the law.

In a March 16, 1997 article in the *Richmond Times-Dispatch* entitled "Prostate Testing Is Opposed," the ACP concluded that there is no evidence that patients benefit from routine screening for prostate cancer and recommend against regular testing for all men. The ACP explained that because of uncertainties in the reliability of the tests and the substantial risks of aggressive early treatment, the organization decided screening should be approached as an "individual decision" of each patient in consultation with his physician.

The NCI and other opponents expressed concern that the PSA test is known to have relatively high "false positive" rates. The NCI noted that PSA tests and DREs may also identify a greater number of medically insignificant tumors, leading to unnecessary emotional trauma for a patient.

Proponents contended that the PSA test, when used in conjuction with the DRE, is the most effective prostate cancer screening available. One prostate cancer survivor noted in written comments that when compared to screenings for breast cancer, the PSA test has a lower "false positive" result. The AFUD submitted comments indicating that prostate cancer screenings encounter between 2.29% to 8% clinically insignificant cancers.

The APS disputes the notion that PSA testing is unnecessary and wasteful. According to the APS, doctors can detect eight of ten prostate cancers with PSA testing before they spread beyond the prostate. Nine of ten prostate cancers caught before they spread can be cured, and the lives of those men saved. Prostate cancer diagnosed after it breaks through the wall of the prostate is beyond a cure. At that point, the cancer can only be slowed, and pain controlled.

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.*

Opponents contended that Senate Bill 1003 is inconsistent with the role of health insurance because it mandates a procedure which has an effectiveness that is questioned. VCC stated in written comments that the bill would compel all purchasers in this market to buy coverage for a test that is not recognized by the American Medical Association as the preferred diagnostic tool for prostate cancer. VAHMO noted in written comments that mandating benefits and practice standards into the insurance code is not sound public policy because it imposes an inflexibility inconsistent with changing medical quidelines.

Proponents argued that Senate Bill 1003 is consistent with the role of health insurance because, like mammography for women, it allows men an opportunity to be diagnosed for a life-threatening disease before it spreads. Citing legislation passed in 1996 mandating coverage for mammography, proponents contended that Senate Bill 1003 would provide the male equivalent of breast cancer screening.

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

Proponents believed that the need for coverage outweighs the costs of mandating the benefit for all poliycholders because it costs less to provide coverage for annual screening than to treat advanced prostate cancer.

Respondents to the Bureau survey provided cost figures of between less than $0.01 and $5.00 per month per standard individual policy and between $0.05 and $5.00 per month per standard group certificate to provide the coverage as specified in Senate Bill 1003. Insurers providing coverage on an optional basis provided cost figures from $0.04 to $10.00 per month for both individual policies and group certificates.

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 than a mandate of coverage because of adverse selection by men with strong family histories of prostate cancer. 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. Therefore, it is possible that many men would not benefit from such a mandate.

RECOMMENDATION

The Advisory Commission voted on September 17, 1997 not to recommend that Senate Bill 1003 be enacted (No - 4, Yes - 4).

CONCLUSION

The Advisory Commission discussed the lack of consensus on the medical efficacy of an annual PSA test conducted in conjunction with a DRE. Some members questioned whether it was medically appropriate to screen every male of a certain age, even if they did not show signs or symptoms of prostate cancer. Other members mentioned evidence indicating that the PSA test, conducted in conjunction with a DRE, is an effective tool for diagnosing early-stage prostate cancer. Some Advisory Commission members also believed that the language in Senate Bill 1003 was ambiguous.

1997 SESSION

978038739

SENATE BILL NO. 1003

Offered January 17, 1997

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 38.2-3418.3, relating to accident and sickness insurance; coverage for annual PSA testing.

Patrons—Stolle, Earley, Howell, Lucas, Norment, Quayle, Saslaw, Schrock and Williams; Delegates: Bryant, Drake, Dudley, Katzen, McDonnell, Purkey and Tata

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Referred to the Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.3 as follows:

§ 38.2-3418.3. Coverage for PSA testing.

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 for annual PSA testing under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1997.

B. For the purpose of this section, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen.

C. The provisions of this section shall not apply to short-term travel, accident only, limited or specified disease policies, or to short-term nonrenewable policies of not more than six months' duration.

§ 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, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 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, Article 4 (§ 38.2-1317 et seq.) of Chapter 13, 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, 38.2-3411.2, 38.2-3414.1, 38.2-3418.1, 38.2-3418.1:1, 38.2-3418.1:2, 38.2-3418.2, *38.2-3418.3*, 38.2-3419.1, 38.2-3431, 38.2-3432, 38.2-3433, 38.2-3500, 38.2-3514.1, 38.2-3514.2, 38.2-3525, 38.2-3542, Chapter 53 (§ 38.2-5300 et seq.) and Chapter 54 (§ 38.2-5400 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.

APPENDIX B

COVERAGE FOR ANNUAL PROSTATE-SPECIFIC ANTIGEN TESTS IN OTHER STATES

STATE	CITATION	SUMMARY
Alaska	21.42.395 (individual, group, nonprofits, HMOs) (1996)	Coverage for an annual prostate cancer screening test for a person at least 40 years of age, but less than 50 years of age, in a high risk group (African-American or who has a family history of prostate cancer). Annual screening for men 50 years of age or older. Patient cannot be denied coverage because he has already had a digital rectal exam and the results were negative.
Colorado	10-16-104 (individual, group) (1996)	Coverage for annual screening for the early detection of prostate cancer in men over the age of 50 years, and in men over the age of 40 years who are in high-risk categories. Coverage shall be the lesser of $65 per prostate cancer screening or the actual charge for such screening. Benefits shall not diminish or limit diagnostic benefits otherwise allowable under the policy. Screening is to be performed by a qualified medical professional. Screening shall consist of, at a minimum, (a) a PSA blood test and (b) a digital rectal examination.
Delaware	18 § 3552 (group) (1988/1995)	Coverage for prostate cancer screening by the PSA test.
Georgia	33-29-3.2 (individual) 33-30-4.2 (group) (1990/1992)	Every insurer issuing policies providing coverage for men must provide coverage for annual PSA tests for covered males 45 years of age or older; or for covered males who are 40 years of age or older, if ordered by a physician.
Minnesota	62Q.50 (1996)	Coverage for prostate cancer screening for men 40 years of age or over who are symptomatic or in a high-risk category, and for all men 50 years of age or older.

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New Jersey	17:48-6p (nonprofit) 17:48A-7n 17:48E-35.13 17B:27-46.10 (group) (1996)	Coverage for expenses incurred in conducting an annual medically recognized diagnostic examination including, but not limited to a digital rectal examination and a PSA test for men age 50 and over who are asymptomatic, and for men age 40 and over with a family history of prostate cancer or other prostate cancer risk factors.
North Carolina	58-51-58 58-65-93 (nonprofit) 58-67-77 (HMO) (1993)	Coverage for PSA tests or equivalent tests for the presence of prostate cancer when recommended by a physician.
North Dakota	26.1-36 (individual, group, nonprofit, HMO) (1997)	Coverage for an annual digital rectal examination and a PSA test for an asymptomatic male aged 50 and over, a black male aged 40 and over, and a male aged 40 or over with a family history of prostate cancer.
Texas	I.C. Art. 26.47 (1995)	Coverage for prostate cancer screening must be provided without copayment or deductibles.
West Virginia	33-15-15 (all policies) (1991/1994)	Coverage for medical and laboratory services in connection with annual check-up for prostate cancer in men age 50 and over.

APPENDIX C

Senate Bill No. 1003

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 38.2-3418.3 as follows:

38.2-3418.3. Coverage for PSA testing **and Digital Rectal Examination**

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; and 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 for ~~annual~~ PSA testing, and **Digital Rectal Examinations, according to American Cancer Society guidelines,** under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1997.

B. For the purpose of this section, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen.

C. The provisions of this section shall not apply to short-term travel, accident only, limited or specific disease policies, or to short-term nonrenewable policies of not more than six months duration.