

II. Present Situation:

Background on Prostate Cancer

Prostate cancer is a common disease among older men. It is second only to lung cancer as the primary cause of cancer deaths among men in the United States. For the general population, a man has about a 16 percent chance (1 in 6) of being diagnosed with prostate cancer in his lifetime and a 3 percent chance (1 in 33) of dying from the disease.¹ Several risk factors increase a man's chances of developing prostate cancer. These include: age, family history, race, and possibly diet. Men who have a father or brother with prostate cancer have a greater chance of developing the disease. African American men have the highest rate of prostate cancer, while Asian and Native American men have the lowest rates. The prostate cancer death rate among African American men is more than twice as high as that of white men, and over three times greater than that of Hispanic men. In addition, there is some evidence that a diet higher in fat, especially animal fat, may increase the risk of prostate cancer.² According to the National Cancer Institute, an estimated 218,890 new cases of prostate cancer will be diagnosed in the United States in 2007. In addition, it is expected that 27,050 deaths will be attributed to the disease this year.

Two procedures currently utilized to detect prostate cancer are the prostate specific antigen (PSA) test and the digital rectal exam (DRE). Prostate specific antigen is a blood protein. Levels of the protein increase when the prostate has cancer or other diseases. The PSA test measures this protein in samples of blood drawn from men who are being screened for prostate cancer. The test results are usually reported as nanograms of PSA per milliliter (ng/ml) of blood. In the past, most doctors considered PSA values below 4.0 ng/ml as normal. However, recent research has found prostate cancer in men with PSA levels below 4.0 ng/ml. Therefore, many doctors are now using the following ranges, with some variation:

- 0 to 2.5 ng/ml is low
- 2.6 to 10 ng/ml is slightly to moderately elevated
- 10 to 19.9 ng/ml is moderately elevated
- 20 ng/ml or more is significantly elevated

There is no specific normal or abnormal PSA level. However, the higher a man's PSA level, the more likely it is that cancer is present. But because various factors can cause PSA levels to fluctuate, one abnormal PSA test does not necessarily indicate a need for other diagnostic tests. When PSA levels continue to rise over time, other tests may be needed.³

Recommendations of American Cancer Society (and other Organizations)

The American Cancer Society provides the following information regarding prostate cancer screening on its website⁴:

¹ Medicare Prostate Cancer Screening, available at: <http://www.medicare.gov/Publications/Pubs/pdf/11042.pdf>

² National Cancer Institute, available at: <http://www.cancer.gov/cancertopics/factsheet/Detection/PSA>

³ National Cancer Institute, available at: <http://www.cancer.gov/cancertopics/factsheet/Detection/PSA>

⁴ http://www.cancer.org/docroot/CRI/content/CRI_2_6x_Prostate_Cancer_Early_Detection.asp?sitearea=&level=

If prostate cancer is detected during routine yearly exams with the PSA test or DRE, your cancer will probably be at an early, more treatable stage.

Since the use of early detection tests for prostate cancer became relatively common (about 1990), the prostate cancer death rate has dropped. However, it has not been proven that this is a direct result of screening. Studies are under way to try to confirm that early detection tests for prostate cancer in large groups of men will lower the prostate cancer death rate.

On the other hand, there are potential problems with the current screening methods. Neither the PSA test nor the DRE is 100 percent accurate. Inconclusive or false results on testing could cause confusion and anxiety. Some men might undergo a prostate biopsy (which carries its own small risks) when cancer is not present, while others might get a false sense of security from normal test results when cancer is actually present.

Until more information is available, you and your doctor must decide whether you should have the PSA test. Major factors to consider are your age and health. If you are young and develop prostate cancer, it will probably shorten your life if it is not caught early. If you are older, or in poor health, then prostate cancer may never become a major problem because it is generally a slow-growing cancer.

The American Cancer Society believes that health care professionals should offer the prostate-specific antigen (PSA) blood test and digital rectal exam (DRE) yearly, beginning at age 50, to men who have at least a 10-year life expectancy. Men at high risk, such as African Americans and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer at an early age (younger than age 65), should begin testing at age 45.

Men at even higher risk (because they have several first-degree relatives who had prostate cancer at an early age) could begin testing at age 40. Depending on the results of this initial test, further testing might not be needed until age 45.

Health care professionals should give men the opportunity to openly discuss the benefits and risks of testing at annual checkups. Men should actively participate in the decision by learning about prostate cancer and the pros and cons of early detection and treatment of prostate cancer.

Recommendations of other organizations: No major scientific or medical organizations, including the American Cancer Society (ACS), American Urological Association (AUA), US Preventive Services Task Force (USPSTF), American College of Physicians (ACP), National Cancer Institute (NCI), American Academy of Family Physicians (AAFP), and

American College of Preventive Medicine (ACPM) advocate routine testing for prostate cancer at this time. The USPSTF has concluded that studies completed so far do not provide enough evidence to determine whether the benefits of testing for early prostate cancer outweigh the disadvantages.

The ACS, AUA, ACP, NCI, AAFP, and ACPM recommend that health care professionals discuss the option of testing for early detection of prostate cancer with men. They recommend discussing the potential benefits, side effects, and unresolved questions regarding early prostate cancer detection and treatment so that men can make individualized and informed decisions about testing. In addition, the American Cancer Society and the American Urological Association, recommend that health care professionals offer the option of testing for early detection of prostate cancer to men who are at least 50 years old (or younger if at higher risk).

Recommendations of National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN), the organization cited in this bill, is a not-for-profit alliance of 20 of the world's leading cancer centers (including the H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida). All member institutions are not-for-profit organizations. According to NCCN⁵:

The NCCN and its Member Institutions are dedicated to improving the quality and effectiveness of care provided to patients with cancer. NCCN develops scientific, evaluative information to inform and improve decisions that can lead to better care. The development of NCCN information is based upon the independent evaluation of available scientific evidence integrated with the expert judgment of leading clinicians. The NCCN is dedicated to the provision of sound, evidenced-based, authoritative recommendations that serve the best interests of patients with cancer. A complete description (Winn, 2003) of the process for the development of the NCCN Clinical Practice Guidelines in Oncology™ is available for review.

The NCCN guidelines, Prostate Cancer Early Detection (2006), are available on its website⁶. However, these guidelines are copyrighted and reproduction is expressly prohibited without written permission of NCCN. Committee staff interprets these guidelines as recommending a baseline DRE and PSA at age 40; if the PSA is lower than 0.6, a follow-up at age 45; and if the PSA is at or below 0.6 at age 45, a DRE and PSA at age 50 and annually thereafter. If the follow-up PSA at age 45 is greater than 0.6, the guidelines recommend an annual DRE and PSA thereafter. However, for African-Americans, all persons with a family history of prostate cancer, and persons who have a PSA equal to or greater than 0.6 for the base line PSA at age 40, the

⁵ <http://www.nccn.org/about/disclosure.asp>

⁶ http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf

guidelines recommend an annual DRE and PSA beginning at age 40. However, this is a broad summary of the guidelines which provide further qualifications and recommendations, including emphasis that any clinician is expected to use independent medical judgment in determining any patient's care.

Other State Laws

The 2006 Health Insurance Mandates in the States report, issued by the Council for Affordable Health insurance, indicates 32 states have insurance law requiring coverage for prostate screening. The majority of those states mandating prostate cancer screening require health insurance contracts to, at a minimum provide coverage to men age 50 and older, while providing coverage at age 40 for those in a high-risk category. There are more progressive variances to some states' law with respect to minimum age for prostate cancer screening coverage. Alaska, for example, has provided minimum coverage requirements to annual screening for two groups of patients: 1) a person who is age 35-40 in a high-risk group and 2) for a person who is 40 or more. Indiana and Maryland require insurance providers to cover prostate cancer screening for men age 40 and over, but do not specify high-risk requirements.

Insurance Coverage in Florida

It appears that health insurance coverage issued in Florida often covers the PSA test and the DRE as medically necessary preventative services for the screening of prostate cancer. However, there exists a disparity as to what age these screening tests should be covered. The Division of State Group Insurance of the Department of Management Services contracts with Blue Cross Blue Shield (BCBS) of Florida to administer the state employees' Preferred Provider Organization (PPO) plan. This plan provides these tests, but limits them to men age 50 and over. High-risk individuals are determined to be so at the discretion of their physician. According to a representative of BCBS, most of their individual, group, and HMO contracts meet these same guidelines for prostate cancer screening. According to information retrieved from Aetna for its health insurance policies, men age 40 and over, and those under the age of 40 who are high risk for prostate cancer, are eligible for annual PSA tests and DREs. Medicare covers both the PSA test and a DRE once every 12 months for all men age 50 and over with Medicare coverage.

III. Effect of Proposed Changes:

Section 1 creates a short title. This section shall be cited as the "Senator Les Miller Act."

Section 2 requires that all individual health insurance policies providing coverage to men age 40 and older must provide coverage for annual screening for prostate cancer according to the prostate cancer early detection guidelines of the National Comprehensive Cancer Network (NCCN). These guidelines generally recommend a baseline PSA and DRE at age 40, and subsequent tests at varying time intervals dependent on various factors. See, "Recommendations of National Comprehensive Cancer Network" in Present Situation, above, for further detail.

The bill mandates coverage for prostate cancer screening consisting of, at minimum, a PSA blood test and the DRE. The bill also states that if a medical practitioner recommends that an

insured, subscriber, or enrollee undergoes a PSA test, coverage may not be denied because that person previously had a DRE and the exam results were negative.

Section 3 makes the same requirements as in section 2 above, but applies them to out-of-state group health insurance policies covering a Florida resident.

Section 4 makes the same requirements as in section 2 above, but applies them to group insurance policies.

Section 5 makes the same requirements as in section 2 above, but applies them to health maintenance organization contracts.

Section 6 provides that the Legislature finds that the provisions of this act fulfill an important state interest. (See, Municipality/County Mandates Restrictions, below).

Section 7 provides that the act shall take effect January 1, 2008, and shall apply to policies or contracts issued or renewed on or after that date.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The health insurance benefit required by this bill applies to local government health insurance plans.

Section 18(a), Art. VII of the State Constitution provides that a city or county is not bound by any general law requiring the city or county to spend funds or to take an action to expend funds unless the Legislature has determined that the law fulfills an important state interest and unless, for purposes relevant to this bill, the expenditure is required to comply with a law that applies to all persons similarly situated or the law requiring the expenditure is approved by two-thirds of the membership of each house of the Legislature.

The bill applies to all similarly situated persons and fulfills an important state interest.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

According to a spokesperson for the National Prostate Cancer Coalition, the most recent study on fiscal impacts of mandated prostate cancer screening comes from the Massachusetts Division of Health Care Finance and Policy in 2004. The Lewin Group performed an actuarial analysis for the Massachusetts Legislature to determine whether health insurance premiums would increase due to a proposed mandate that required prostate cancer screening for all men age 40, and all men, regardless of age, who have a history of prostate cancer. Their findings indicated that all major carriers in Massachusetts already covered the two main screening tests. Officials responsible for the study did not think it seemed likely that passage of these proposals would add much to the cost of premiums. The Lewin Group's best estimate of increased premium costs per member, per year was \$0.16. However, if there was a substantial increase in the number of men tested, the Lewin Group officials felt that there would likely be an increase in the number of follow-up exams, tests, and biopsies, some of which would be lifesaving, and others of which would prove to be unnecessary. Those cost estimates provided did not include indirect costs of additional biopsies, exams, and tests that may have resulted from increased utilization of PSA tests.

According to the Office of Insurance Regulation's analysis of the bill, increased claims costs arising from this legislation will be passed through to all policyholders and/or subscribers in the form of increased health insurance plan premium cost. However, the extent to which plan premium costs would rise in Florida is indeterminate. A representative of BCBS stated that prostate cancer screening tests, including both the PSA test and DRE, usually run between \$30 and \$40 for the tests, but requires an analysis by a doctor or professional staff, which is on average priced at \$288.

C. Government Sector Impact:

According to representatives of the Department of Management Services, the State Group Health Insurance Program will be required to expand its covered benefits. For Plan Year 2008, the projected increased Trust Fund cost for the PPO Plan would be in excess of \$230,000. The magnitude of cost increases attributable to increased HMO premiums could be similar. The HMO costs can not be accurately predicted since contractual arrangements between individual HMOs and providers may vary by HMO and by contracted provider. Negotiations with the state contracted HMOs for calendar year 2008 rates have not begun.

The estimated annual recurring impact to the State Employees Health Insurance Trust Fund is \$460,000.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Pursuant to s. 624.215, F.S., every person seeking consideration of a legislative proposal, which would mandate health coverage by an insurer, health care service contractor, or health maintenance organization, shall submit to the legislative committees having jurisdiction a report, which assesses the social and financial impacts of the proposed coverage.

A report was not filed addressing the specific items listed in this statute, but the bill sponsor provided committee staff with a 2004 actuarial study of the fiscal impacts of mandated prostate cancer screening by the Lewin Group for the Massachusetts Division of Health Care Finance and Policy, summarized in Private Sector Impact, above.

VIII. Summary of Amendments:

None.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
