The Florida Senate

PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Policy Committee

BILL:	CS/SB 110
INTRODUCER:	Banking and Insurance Committee and Senator Hill and others
SUBJECT:	Health Insurance/Prostate Cancer Coverage
DATE:	April 5, 2007 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peacock	Deffenbaugh	BI	**Fav/CS**
2.	Garner	Wilson	HP	**Favorable**
3.			GA	
4.				
5.				
6.				

I. Summary:

The bill specifies that this act may be cited as the "Senator Les Miller Act."

The bill requires all individual, group, and out-of-state group health insurance policies, as well as all health maintenance organization (HMO) contracts, which cover a man age 40 or over to provide coverage for an annual screening for prostate cancer, according to the early detection guidelines of the National Comprehensive Cancer Network.

The bill provides that the coverage for prostate cancer screening must consist of, at minimum, a prostate specific antigen (PSA) blood test and a digital rectal exam (DRE). If a medical practitioner recommends that an insurer, subscriber, or enrollee undergo a PSA test, coverage may not be denied because that person previously had a DRE with negative results.

This bill creates ss. 627.64091 and 627.6418, F.S. The bill also amends ss. 627.6515 and 641.31, F.S.

II. Present Situation:

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. 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.

Prostate Cancer Screening

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 the PSA levels to fluctuate, one abnormal PSA test does not necessarily indicate a need for other diagnostic tests. When the PSA levels continue to rise over time, other tests may be needed.[2]

The use of the DRE and PSA tests as diagnostic tools for prostate cancer is somewhat controversial. This is because it is not yet known if these test actually saves lives. Neither of the screening tests for prostate cancer is perfect. Most men with mildly elevated PSA levels do not have prostate cancer, and many men with prostate cancer have normal levels of PSA. Also, the DRE can miss many prostate cancers. The DRE and PSA test together are better than either test alone in detecting prostate cancer.[3]

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[1] Medicare Prostate Cancer Screening, available at: http://www.medicare.gov/Publications/Pubs/pdf/11042.pdf (last visited on April 5, 2007)
[2] National Caner Institute, available at: http://www.cancer.gov/cancertopics/factsheet/Detection/PSA (last visited on April 5, 2007)
[3] National Cancer Institute, available at: http://www.cancer.gov/cancertopics/factsheet/Detection/early-prostate (last visited on April 5, 2007)

Moreover, it is not clear if the benefits of the PSA screening outweigh the risks of follow-up diagnostic tests and cancer treatments. For example, the PSA test may detect small cancers that would never become life threatening. This over diagnosis of prostate cancer puts men at risk for complications from unnecessary treatment such as surgery or radiation.

Furthermore, if the test indicates elevated PSA levels, additional diagnostic procedures are usually performed. The most accurate procedure used to diagnose prostate cancer (prostate biopsy) may cause side effects, including bleeding and infection. Prostate cancer treatment may cause incontinence (inability to control urine flow) and erectile dysfunction (erections inadequate for intercourse). For these reasons, it is important that the benefits and risks of diagnostic procedures and treatment be taken into account when considering whether to undertake prostate cancer screening.[4]

Recommendations of the National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN), the organization cited in this bill, is a not-for-profit alliance of twenty 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 NCCN:[5]

> *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 website.[6] 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 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.

[4] National Cancer Institute. http://www.cancer.gov/cancertopics/factsheet/Detection/PSA (last visited on April 5, 2007)
[5] http://www.nccn.org/about/disclosure.asp (last visited on April 5, 2007)
[6] http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf (last visited on April 5, 2007)

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.[7] 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

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. Florida Medicaid recommends a PSA test for men 50 years and older as deemed medically necessary.

III. Effect of Proposed Changes:

Section 1. Creates a short title authorizing the act to be cited as the "Senator Les Miller Act."

Section 2. Creates s. 627.64091, F.S., requiring 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); requiring that coverage for prostate cancer screening consist of, at minimum, a PSA blood test and the DRE; specifying 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; and specifying that the benefits required by this section do not limit diagnostic benefits otherwise allowable under the policy.

[7] Council for Affordable Health Insurance. http://www.cahi.org/cahi_contents/resources/pdf/MandatePub2006.pdf (last visited on April 5, 2007)

Section 3. Amends s. 627.6515, F.S., establishing 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. Creates s. 627.6418, F.S., establishing the same requirements as in section 2 above, but applies them to group insurance policies.

Section 5. Amends s. 641.31, F.S., establishing 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.

Section 7. Provides that the bill takes 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:

Inasmuch as this bill requires local governments to incur expenses to pay additional health insurance costs, the bill falls within the purview of s. 18, Art. VII of the State Constitution, which provides that cities and counties are not bound by general laws requiring them to spend funds or to take an action which requires the expenditure of funds unless certain specified conditions are met. One condition that must be met is that the Legislature has determined that the law fulfills an important state interest. The bill contains an express legislative determination to this effect. In addition, one of various other conditions must be met, including (among others), approval by a two-thirds vote of the membership of each house of the Legislature for passage; or that the expenditure is required to comply with a law that applies to all persons similarly situated, including the state and local government.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

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 the 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. Since the U.S. Preventive Task Force and the American Academy of Family Physicians found insufficient evidence to recommend for or against the screenings specified, any expenses may not be offset by resulting savings or future cost avoidance.

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.