

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-- The bill expands coverage for prostate cancer screening for men 40 and older.

B. EFFECT OF PROPOSED CHANGES:

BACKGROUND

Background on Prostate Cancer

Prostate cancer is second only to lung cancer as the primary cause of cancer deaths among men in the United States.¹ Among all causes of death in men over age 45, prostate cancer ranks fifth.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; 27,050 deaths will be attributed to prostate cancer.

In 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.³ Age, family history, race, and possibly diet increase a man's chances of developing prostate cancer. There is some evidence that a diet higher in fat, especially animal fat, may increase the risk.⁴

Moreover, men who have a father, brother, or son with prostate cancer have a greater chance of developing the disease. "African American men are diagnosed with prostate cancer at a rate nearly 50 percent higher than white men, more than twice as high as Hispanic men, nearly three times higher than Asian/Pacific Islanders, and nearly five times higher than Native American men."⁵

Two procedures currently utilized to detect prostate cancer are the prostate specific antigen (PSA) test and the digital rectal exam (DRE).⁶ 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. According to the National Cancer Institute, 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, the Institute reports, 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 elevated⁷

¹ National Conference of State Legislatures, Prostate Cancer Screening Mandates, available at: <http://www.ncsl.org/programs/health/prostate.htm>

² (1) Heart disease, (2) lung cancer, (3) stroke, (4) emphysema, (5) prostate cancer, (6) pneumonia, (7) diabetes, (8) unintentional injuries, (9) colorectal cancer, and (10) liver disease are the top 10 causes of death among men age 45 and older.

³ Centers for Disease Control and Prevention, Prostate Cancer Screening: A Decision Guide, available at: <http://www.cdc.gov/cancer/prostate/publications/decisionguide/>

⁴ National Cancer Institute, available at: <http://www.cancer.gov/cancertopics/factsheet/Detection/PSA>

⁵ National Conference of State Legislatures, Prostate Cancer Screening Mandates, available at: <http://www.ncsl.org/programs/health/prostate.htm>

⁶ National Cancer Institute, What You Need to Know About Prostate Cancer, available at: <http://www.cancer.gov/cancertopics/wyntk/prostate/page5>

There is no specific normal or abnormal PSA level. Although, a higher PSA level tends to increase the likelihood that cancer is present. However, because a variety of factors such as benign prostate enlargement, inflammation, infection, age, and race can cause elevated PSA levels, one abnormal PSA test does not necessarily indicate a need for other diagnostic tests.⁸ Nonetheless, when PSA levels continue to rise over time, other tests may be needed.⁹

Recommendations of American Cancer Society (and other Organizations)

The American Cancer Society provides the following information regarding prostate cancer screening on its website:¹⁰

Men who have at least a 10-year life expectancy should have a PSA blood test and a DRE yearly beginning at age 50. Testing of high-risk men is recommended beginning at age 45. Additionally, men who are considered to be exceptionally high-risk could begin testing at age 40, with the results determining whether another test is needed before age 45.

While it notes that the death rate has dropped since the early detection tests became commonplace, the American Cancer Society states that research has not proven that the direct cause of this improvement is screening, and that more studies are needed.

The website also notes that “[n]o 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.”¹¹

Recommendations of National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN), the organization whose guidelines are 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.¹²

The NCCN guidelines, Prostate Cancer Early Detection (2006), are available on its website.¹³ 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, with the results determining whether a follow-up is necessary annually or not again until age 45. However, for high-risk persons (those who have a strong family history, are African American, or have a baseline PSA above a certain level), an annual DRE and PSA should be done 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.

⁷ National Cancer Institute, The Prostate-Specific Antigen (PSA) Test: Questions and Answers, available at: <http://www.cancer.gov/cancertopics/factsheet/Detection/PSA>

⁸ Id.

⁹ Id.

¹⁰ American Cancer Society, Prostate Cancer: Early Detection: Importance of Finding Prostate Cancer Early, available at: http://www.cancer.org/docroot/CRI/content/CRI_2_6x_Prostate_Cancer_Early_Detection.asp?sitearea=&level=

¹¹ Id.

¹² The National Comprehensive Cancer Network, available at: <http://www.nccn.org/about/disclosure.asp>

¹³ The National Comprehensive Cancer Network, available at http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf

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.¹⁴ While 50 years of age and older is the common trigger for mandated screening coverage, some states, such as Colorado, Kansas, North Dakota, Oklahoma, and Virginia, require screening coverage for men 40 years of age and older when they are in a high-risk category due to ethnicity or family history.¹⁵ Both Indiana and Maryland require, without qualification, prostate cancer screening coverage for men who are 40 years of age and older.¹⁶ Alaska also requires screening coverage for all men who are 40 years of age and older, and also for men who are at least 35 and are in a high-risk category.¹⁷

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, health plan guidelines differ on the age at which these screening tests should be covered.

For men who are covered by Medicare, guidelines permit a PSA blood test and a DRE every year.¹⁸ If a doctor deems it necessary for diagnostic reasons, Medicare will also cover more frequent testing.¹⁹

According to an Agency for Health Care Administration (AHCA) representative, Florida's Medicaid program covers the tests outlined in the bill for all men, regardless of age, with no other criteria or qualifications.

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.

PROPOSED CHANGES

The bill, cited as the "Senator Les Miller Act," requires that a health benefit plan that is offered, issued, or renewed in Florida on or after January 1, 2008, which provides 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).²⁰ These guidelines generally recommend a baseline PSA and DRE at age 40, and subsequent tests at varying time intervals dependent on various factors.

¹⁴ Report available at link provided on the following website: http://www.sbhpsnow.com/object/IO_23643.html

¹⁵ National Conference of State Legislatures, Prostate Cancer Screening Mandates, available at:

<http://www.ncsl.org/programs/health/prostate.htm>

¹⁶ Id.

¹⁷ Id.

¹⁸ Medicare Preventive Services, Prostate Cancer Screening, available at: <http://www.medicare.gov/health/prostate.asp>

¹⁹ American Cancer Society, Medicare Coverage for Cancer Prevention and Early Detection, available at:

http://www.cancer.org/docroot/PED/content/PED_2_3x_Cancer_Screening_-_Medicare_Coverage.asp

²⁰ No report was submitted to AHCA in compliance with section 624.215, Florida Statutes, which requires that every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, health care service contractor, or health maintenance organization as a component of individual or group policies.

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 undergo a PSA test, coverage may not be denied because that person previously had a DRE and the exam results were negative. Additionally, the screening benefit required by the bill does not limit diagnostic benefits otherwise allowed under a health benefit plan.

The bill defines health benefit plan as:

- group hospital or medical insurance coverage,
- a not for-profit hospital or medical service or indemnity plan,
- a prepaid health plan,
- a health maintenance organization plan,
- a preferred provider organization plan,
- a state or municipal employee health insurance plan,
- a program funded under Title XIX (Medicare or Medicaid) of the Social Security Act or other publicly funded program,
- a Multiple Employer Welfare Arrangement, or
- an employee self-insured plan, except as exempt under federal ERISA provisions.

The bill excludes the following from the definition of health benefit plan:

- short-term, accident, fixed indemnity, or specified disease policies,
- disability income contracts,
- limited benefit or credit disability insurance,
- workers' compensation insurance,
- automobile medical payment insurance, or
- insurance under which benefits are payable without regard to fault and which is required by law to be included in a liability insurance policy or equivalent self-insurance.

The bill provides an effective date of January 1, 2008.

C. SECTION DIRECTORY:

Section 1: Provides that the act may be cited as the "Senator Les Miller Act."

Section 2: Requires health benefit plans, as defined in the bill, to offer coverage for prostate cancer screening for men age 40 and over.

Section 3: Provides effective date of January 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DMS estimates that it will incur at least a \$230,000 fiscal impact as a result of increased Trust Fund costs for the state PPO plan.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Please see comments below relating to Applicability of Municipality/County Mandates Provision.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private health benefit plan providers may incur additional costs of the required procedures and any related treatment or procedures. These costs may be passed on to plan participants. These costs however, may be offset by savings from procedures and treatments that would have occurred in the absence of the required screenings.

D. FISCAL COMMENTS:

Although unable to predict exact costs to HMOs, DMS estimates that the cost would be similar to that incurred by the state PPO (\$230,000). Specific costs are unable to be determined because contractual arrangements between individual HMOs and providers may vary by HMO and contracted provider, and negotiations with the state-contracted HMOs for calendar year 2008 have not begun. DMS also notes that expenses may not be offset by resulting savings or future cost avoidance because the U.S. Preventive Task Force and the American Academy of Family Physicians found insufficient evidence to recommend for or against the prostate cancer screenings as provided for in the bill.

The Agency for Health Care Administration (AHCA) has indicated that this bill will have no impact on Medicaid. Currently, Medicaid covers the tests outlined in the bill for all men, regardless of age, with no other criteria or qualifications.

OIR will not incur a fiscal impact. Although this bill will result in new contract/rate filings by insurers, OIR indicates that it can absorb the resultant workload with current resources.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The mandates provision appears to apply because to this bill because it requires counties or municipalities to spend funds or to take an action requiring the expenditure of funds; however, an exemption applies if a bill contains a statement of important state interest and the provisions of the bill apply to all persons similarly situated. State government and all local governments, not just counties and municipalities, are subject to the screening coverage requirement, thereby satisfying one part of the exemption. However, the bill does not currently contain a statement of important state interest; therefore, the bill as drafted requires a two-thirds vote of the membership of each house.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not specify where the language should be included in the Insurance Code. OIR recommends the following:

- a. Add provision relating to individual health insurance policies to Part VI of chapter 627, Florida Statutes;
- b. Add provision relating to group health insurance policies to Part VII of chapter 627, Florida Statutes;
- c. Add provision relating to HMOs to chapter 641, Florida Statutes;
- d. Add provision relating to standardized small group policies to section 627.6699, Florida Statutes;

Add provision relating to policies issued out of state but marketed to Florida residents to section 627.6515, Florida Statutes.

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On April 20, 2007, the Jobs & Entrepreneurship Council adopted two amendments:

Amendment #1: Names the Act the "Senator Les Miller Act."

Amendment #2: Removed the requirement from the bill that the coverage not be subject to deductibles.