

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 1300

INTRODUCER: Health Regulation Committee and Senator Hill and others

SUBJECT: Prostate Cancer Awareness Program

DATE: April 9, 2010 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Bell	Wilson	HR	Fav/CS
2.			HE	
3.			HI	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

- | | | |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes |
| B. AMENDMENTS..... | <input type="checkbox"/> | Technical amendments were recommended |
| | <input type="checkbox"/> | Amendments were recommended |
| | <input type="checkbox"/> | Significant amendments were recommended |

I. Summary:

The Committee Substitute (CS) for Senate Bill 1300 transfers the responsibility for the Prostate Cancer Awareness Program from the Department of Health (Department) to the University of Florida Prostate Disease Center (UFPDC). The purpose of the Prostate Cancer Awareness Program is modified to include: the reporting of recent prostate cancer research and availability of clinical trials; minimizing health disparities; and communicating best-practice principles to physicians treating prostate cancer patients. The bill changes the name of the Prostate Cancer Advisory Committee to the UFPDC Prostate Cancer Task Force (Task Force) that will be administered by the UFPDC in collaboration with the Department.

The duties of the Task Force include: providing prostate cancer education to the community; verifying the accuracy of prostate cancer information disseminated to the public; hosting an annual prostate cancer symposium; and submitting a prostate cancer annual report to the Governor and Legislature.

This bill substantially amends s. 381.911, F.S.

II. Present Situation:

Prostate Cancer

The prostate is a gland in the male reproductive system. Cancer of the prostate is a disease in which cancer cells are found in the prostate. The prostate makes and stores a component of semen and is located in the pelvis, under the bladder and in front of the rectum. The prostate surrounds part of the urethra, the tube that empties urine from the bladder. Because of the prostate's location, the flow of urine can be slowed or stopped if the prostate grows too large. Symptoms of prostate cancer may include: weak or interrupted flow of urine, frequent urination, trouble urinating, pain or burning during urination, blood in the urine or semen, a pain in the back, hip, or pelvis that does not go away, and painful ejaculation.¹

Two tests are used to detect prostate cancer in the absence of symptoms. One is the digital rectal exam, in which a doctor feels the prostate through the rectum to find hard or lumpy areas. The other is a blood test used to detect a substance made by the prostate called prostate-specific antigen (PSA). However, an elevated PSA is not always a sign of prostate cancer. Together, these tests can detect many silent prostate cancers. Due to the widespread implementation of PSA testing in the United States, approximately 90 percent of all prostate cancers are diagnosed at an early stage.²

The diagnosis of prostate cancer must be confirmed by a biopsy. A needle biopsy of the prostate is usually conducted by a urologist under local anesthesia. A pathologist then tests the extracted prostate cells for cancer. The severity of prostate cancer is described by grade and stage. The prostate cancer grade describes how closely the tumor resembles normal prostate tissue. A higher grade represents a prostate cancer that generally will grow quicker and spread more quickly. The stage of the prostate cancer corresponds with the extent of the disease. Early prostate cancer, stage I and II, is localized. Stage III and IV prostate cancer extends outside the prostate gland.

Localized prostate cancer is generally treated by:

- Radical prostatectomy, a surgical procedure to remove the entire prostate gland and nearby issues;
- Radiation therapy involving the delivery of radiation energy to the prostate; and
- Active surveillance (watchful waiting).³

Except for skin cancer, cancer of the prostate is the most common malignancy in American men and is the second leading cause of cancer deaths among men in the United States after lung cancer.⁴ More than 70 percent of all clinically diagnosed prostate cancers occur in men over age

¹ National Cancer Institute, Prostate Cancer Treatment, November 18, 2009. Found at: <http://www.cancer.gov/cancertopics/pdq/treatment/prostate/patient/allpages> (Last visited on April 1, 2010).

² National Cancer Institute, Early Prostate Cancer: Questions and Answers. Found at: <http://www.doh.state.fl.us/Family/menshealth/prostatecancerqa.pdf> (Last visited on April 1, 2010).

³ National Cancer Institute, Early Prostate Cancer: Questions and Answers. Found at: <http://www.doh.state.fl.us/Family/menshealth/prostatecancerqa.pdf> (Last visited on April 1, 2010).

⁴ U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 1999–2006 Incidence and Mortality Web-based Report*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2010. Found at: <http://apps.nccd.cdc.gov/uscs/toptencancers.aspx> (Last visited on April 1, 2010).

65.⁵ Risk factors associated with prostate cancer include older age, a family history of the disease, black race, and dietary factors.⁶ In the United States in 2006, 203,415 men developed prostate cancer, and 28,372 men died from prostate cancer.⁷ In Florida in 2006, there were 14,043 new prostate cancer cases diagnosed among males in Florida, and 2,079 males died of prostate cancer.⁸ The incidence rate of prostate cancer in Florida in 2006 was 48 percent higher among black men than white men.

Prostate Cancer Screening Recommendations

In its most recent prostate cancer screening recommendations, the United States Preventive Services Task Force (USPSTF) concluded that it may not be beneficial for men under the age of 75 to be screened for prostate cancer and that for men over the age of 75 there is moderate certainty that the harms of screening for prostate cancer outweigh the benefits.⁹ The USPSTF found convincing evidence that treatment for prostate cancer detected by screening causes moderate to substantial harms, such as erectile dysfunction, urinary incontinence, bowel dysfunction, and death. These harms are especially important because some men with prostate cancer who are treated would never have developed symptoms related to cancer during their lifetime. The USPSTF suggests that a clinician should not order a PSA test without first discussing with the patient the potential but uncertain benefits and known harms of prostate cancer screening and treatment.

The American Cancer Society (ACS) recommends that men have a chance to make an informed decision with their health care provider about whether to be screened for prostate cancer. The prostate cancer screening decision should be made after getting information about the uncertainties, risks, and potential benefits of prostate cancer screening.¹⁰ The ACS recommends that men thinking about prostate cancer screening should make informed decisions based on available information, discussion with their doctors, and their own views on the benefits and side effects of screening and treatment.

The Department of Health

Section 20.43, F.S., creates the Department. The Department is responsible for the state's public health system, which is designed to promote, protect, and improve the health of all people in the state. The mission of the state's public health system is to foster the conditions in which people can be healthy, by assessing state and community health needs and priorities through data collection, epidemiologic studies, and community participation; by developing comprehensive public health policies and objectives aimed at improving the health status of people in the state;

⁵ National Cancer Institute, Early Prostate Cancer: Questions and Answers. Found at: <http://www.cancer.gov/cancertopics/factsheet/Detection/early-prostate> (Last visited on April 1, 2010).

⁶ Florida Department of Health, Bureau of Epidemiology, Prostate Cancer in Florida 2006. Found at: http://www.doh.state.fl.us/disease_ctrl/epi/cancer/Prostate_06.pdf (Last visited April 1, 2010).

⁷ Centers for Disease Control and Prevention, Prostate Cancer, Fast Facts. Found at: http://www.cdc.gov/cancer/prostate/basic_info/fast_facts.htm (Last visited on April 1, 2010).

⁸ Florida Department of Health, Bureau of Epidemiology, Prostate Cancer in Florida 2006. Found at: http://www.doh.state.fl.us/disease_ctrl/epi/cancer/Prostate_06.pdf (Last visited April 1, 2010).

⁹ U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force, Screening for Prostate Cancer Recommendation Statement, August 2008. Found at: <http://www.ahrq.gov/clinic/uspstf08/prostate/prostaters.htm> (Last visited April 1, 2010).

¹⁰ American Cancer Society, Prostate Cancer Detailed Guide, recommendations for prostate cancer early detection. Found at: <http://documents.cancer.org/117.00/117.00.pdf> (Last visited on April 1, 2010).

and by ensuring essential health care and an environment which enhances the health of the individual and the community. The State Surgeon General is the State Health Officer and the head of the Department.

The primary focus of the Department's Men's Health Initiative, located within the Adult and Community Health Unit of the Division of Family Health Services, is to increase awareness about men's health issues and educate men and their families about the importance of screening and early detection in preventing and treating disease among men and boys.¹¹ The Men's Health Initiative provides prostate cancer awareness, screening, and risk factor information.

Cancer Control and Research Act

The Cancer Control and Research Act (the Act) is created in s. 1004.435, F.S. The Florida Cancer Control and Research Advisory Council (C-CRAB) is established within the Act to advise the Board of Governors, the State Surgeon General, and the Legislature on cancer control and research in this state. The C-CRAB consists of 34 members. The C-CRAB annually approves the Florida Cancer Plan. Additional responsibilities of the C-CRAB include:

- Recommending to the State Surgeon General a plan for the care and treatment of persons suffering from cancer and standard requirements for cancer units in hospitals and clinics in Florida;
- Recommending grant and contract awards for the planning, establishment, or implementation of programs in cancer control or prevention, cancer education and training, and cancer research;
- Pursuant to Legislative appropriations, providing written summaries that are easily understood by the average adult patient, informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening of the medically viable treatment alternatives available to them and explaining the relative advantages, disadvantages, and risks associated therewith;
- Implementing an educational program for the prevention of cancer and its early detection and treatment;
- Advising the Board of Governors and the State Surgeon General on methods of enforcing and implementing laws concerning cancer control, research, and education; and
- Recommending to the Board of Governors or the State Surgeon General rulemaking needed to enable the C-CRAB to perform its duties.

Prostate Cancer Awareness Program

In 2004, the Legislature created the Prostate Cancer Awareness Program within the Department.¹² To the extent that funds are made available, the Program is charged with implementing the recommendations of the January 2000 Florida Prostate Cancer Task Force and to provide for statewide outreach and health education activities to ensure men are aware of and appropriately seek medical counseling for prostate cancer as an early detection health care measure.¹³ The Department is required to coordinate its Prostate Cancer Awareness Program with the efforts of the Florida Public Health Institute, Inc.

¹¹ The Department of Health, Men's Health Initiative. Found at: <<http://www.doh.state.fl.us/family/menshealth/index.html>> (Last visited on April 1, 2010).

¹² Section 14, Ch. 2004-2, Laws of Florida.

¹³ Section 381.911, F.S.

The Prostate Cancer Advisory Committee is created in law to assist the Department and the Florida Public Health Institute, Inc. in implementing the Prostate Cancer Awareness program. The State Surgeon General is responsible for appointing the following advisory committee members:

- Three persons from prostate cancer survivor groups or cancer-related advocacy groups;
- Three persons who are scientists or clinicians from public universities or research organizations; and
- Three persons who are engaged in the practice of a cancer related medical specialty from health organizations committed to cancer research and control.

In 2004, the Legislature provided funding for the Department for prostate cancer education and the Department convened a meeting of the Prostate Cancer Advisory Committee.¹⁴ No additional funds have been appropriated for the Prostate Cancer Awareness program and the Committee has not met since 2004.

University of Florida Prostate Disease Center

The UFPDC was established on February 2, 2009 to promote the collaboration of academic and industry partners and focus on discovering new and better diagnostic tools and treatment methods for patients suffering from prostate cancer.¹⁵ The UFPDC is focused on:

- The study of immune mediators and their interactions with benign and malignant prostate cells;
- Identification of cancer genes or gene products that can be exploited for molecular diagnosis and therapy;
- Investigation of the prostate microenvironment including the initiation of a vascular and immunosuppressive network; and
- Exploration of the role of prostate stem cells in the development and progression of prostate disease.

Statutory Requirements Relating to Advisory Councils and Committees

Section 20.03(7), F.S., defines “advisory council” to mean “an advisory body created by specific statutory enactment and appointed to a function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.” Section 20.052, F.S., establishes requirements for advisory bodies created by a specific statutory enactment. An advisory body may not be created unless:

- It meets a statutorily defined purpose;
- Its powers and responsibilities conform with the definitions for governmental units in s. 20.03, F.S.;
- Its members, unless expressly provided otherwise in the State Constitution, are appointed for 4-year staggered terms; and
- Its members, unless expressly provided otherwise by specific statutory enactment, serve without additional compensation or honorarium, and are authorized to receive only per diem and reimbursement for travel expenses as provided in s. 112.061, F.S.

¹⁴ Ch. 2004-268, Laws of Florida.

¹⁵ Board of Governors, SB 1300 Legislative Bill Analysis, on file with the Senate Health Regulation Committee.

Section 20.03(8), F.S., defines “committee” or “task force” to mean “an advisory body created without specific statutory enactment for a time not to exceed one year or created by specific statutory enactment for a time not to exceed 3 years and appointed to study a specific program and recommend a solution or policy alternative with respect to that solution.” A committee or task force terminates when the assignment is completed.

III. Effect of Proposed Changes:

The CS amends s. 381.911, F.S., to transfer the responsibility for the Prostate Cancer Awareness Program from the Department to the UFPDC. The UFPDC is authorized to work with other organizations and institutions to create a systemic focus on increasing community education and awareness about prostate cancer.

The CS changes the name and modifies the responsibilities of the Prostate Cancer Advisory Committee, which is renamed as the UFPDC Prostate Cancer Task Force (Task Force). The Task Force is created to develop and implement strategies to improve early detection of prostate cancer and to reduce the number of patients who succumb to prostate cancer.

The CS provides that that Task Force will:

- Make policy recommendations to the Department, and other governmental entities, on prostate cancer;
- Verify the accuracy of prostate cancer information disseminated to the public;
- Develop effective communication channels among all private and public entities across the state which are involved in education, research, treatment, and patient advocacy;
- Plan, develop, and implement activities designed to heighten awareness and educate residents of the state regarding the importance of early detection and effective treatment options for prostate cancer;
- Develop effective communication channels to various stakeholders within and across the state;
- Disseminate information on recent progress in prostate cancer research and the availability of clinical trials;
- Minimize health disparities through outreach, education, and early detection initiatives;
- Establish a communication platform for patients and their advocates;
- Conduct an annual prostate cancer symposium; and
- Submit an annual report to the State Surgeon General, the Governor and the Legislature by January 15, 2011, that will include legislative recommendations to decrease the incidence of prostate cancer, decrease racial and ethnic disparities, and promote community education and awareness.

The CS specifies that the State Surgeon General will appoint geographically and institutionally diverse Task Force members in consultation with the Comprehensive Cancer Control program within the Department and the Florida Cancer Control Program. The Governor, the Speaker of the House of Representatives, and the Senate President are each required to appoint two Task Force members, as specified in the CS. In addition, Task Force members will serve 4-year terms, but the initial members will have staggered terms. The Task Force will meet at least twice a year.

The effective date of the CS is July 1, 2010.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

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. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians may see additional prostate cancer screening workload.

C. Government Sector Impact:

The Board of Governor's has indicated that the UFPDC will be able to provide prostate cancer education, conduct an annual prostate cancer symposium, and submit a prostate cancer annual report within existing resources.¹⁶

VI. Technical Deficiencies:

Lines 100-106 of the bill, direct the State Surgeon General to appoint members to the Task Force. However, on lines 119-136 Task Force members are appointed by the Speaker of the House of Representatives, the Senate President, and the Governor.

VII. Related Issues:

Current law, as contained in lines 67-68 of the bill, specifies that the purpose of the Prostate Cancer Awareness Program is to implement the January 2000 Florida Prostate Cancer Task Force recommendations. The recommendations from 2000 are outdated and do not incorporate the most recent prostate cancer screening, treatment, or educational recommendations.

¹⁶ Board of Governors, SB 1300 Legislative Bill Analysis, on file with the Senate Health Regulation Committee.

Some of the Task Force responsibilities outlined in the bill are duplicative. For instance, on lines 166-169 of the bill the Task Force is directed to, “develop effective communication channels among all private and public entities across the state which are involved in prostate cancer education, research, treatment, and patient advocacy,” and on lines 175-176 the Task Force is directed to, “develop effective communication channels to various stakeholders within and across the state.”

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on April 7, 2010:

- Transfers the responsibility for the Prostate Cancer Awareness Program from the Department to the UFPDC.
- Changes the name of the Prostate Cancer Advisory Committee to the UFPDC Prostate Cancer Task Force to be administered by the UFPDC in collaboration with the Department.
- Provides for the appointment of members to the Task Force and Task Force duties.

B. Amendments:

None.