

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 414

INTRODUCER: Health Regulation Committee and Senator Oelrich

SUBJECT: Prostate Cancer Awareness Program

DATE: February 8, 2011 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	Fav/CS
2.	_____	_____	BC	_____
3.	_____	_____	RC	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE..... Statement of Substantial Changes

B. AMENDMENTS..... Technical amendments were recommended

Amendments were recommended

Significant amendments were recommended

I. Summary:

The committee substitute (CS) for SB 414 modifies the purpose of the Prostate Cancer Awareness Program (Program), housed within the Department of Health (DOH), to include: promoting prostate cancer awareness; communicating the advantages of early detection; reporting of recent progress in prostate cancer research and availability of clinical trials; minimizing health disparities; communicating best-practice principles to physicians treating prostate cancer patients; and establishing a communication platform for patients and their advocates.

The CS authorizes the University of Florida Prostate Disease Center (UFPDC) to work with other agencies, organizations, and institutions to implement the Program. The CS directs the UFPDC to establish and lead a UFPDC Prostate Cancer Advisory Council (Advisory Council), which replaces the prostate cancer advisory committee. The CS provides for the appointment of members to the Advisory Council, the term-limits of the members, meeting requirements, and the duties of the Advisory Council.

This CS 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 produces and stores a fluid that is 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, or a pain in the back, hip, or pelvis that does not go away.¹

Four 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. Another 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. Also, a transrectal ultrasound may be performed by a doctor using a finger-size probe to examine the prostate through the rectum. Finally, a doctor may perform a biopsy by removing cells or tissues so they can be viewed under a microscope by a pathologist. The pathologist will examine the biopsy sample to check for cancer cells and determine the Gleason score. The Gleason score ranges from 2-10 and describes how likely it is that a tumor will spread. The lower the number, the less likely the tumor is to spread.² All diagnoses of prostate cancer must be confirmed by a biopsy. 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.³

Treatment of prostate cancer corresponds with the stage of the disease and how far the cancer has progressed. Early prostate cancer, stage I and II, is localized. Stage III and IV prostate cancer extends outside the prostate gland.⁴

Localized prostate cancer is generally treated by:

- Radical prostatectomy, a surgical procedure to remove the entire prostate gland and nearby tissues;
- Radiation therapy involving the delivery of radiation energy to the prostate; and
- Active surveillance (watchful waiting).⁵

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

¹ National Cancer Institute, *Prostate Cancer Treatment*, November 5, 2010, available at <http://www.cancer.gov/cancertopics/pdq/treatment/prostate/patient/allpages> (Last visited on February 2, 2011).

² *Id.*

³ National Cancer Institute, *Early Prostate Cancer: Questions and Answers*, available at <http://www.doh.state.fl.us/Family/menshealth/prostatecancerqa.pdf> (Last visited on February 2, 2011).

⁴ *Supra* fn. 1.

⁵ *Supra* fn. 3.

cancer.⁶ More than 70 percent of all clinically diagnosed prostate cancers occur in men over age 65.⁷ Risk factors associated with prostate cancer include older age, a family history of the disease, black race, and dietary factors.⁸ In 2007, there were 223,307 men in the United States who developed prostate cancer, and 29,093 men in the United States died from prostate cancer.⁹ 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.¹⁰ The incidence rate of prostate cancer in Florida in 2006 was 48 percent higher among black men than white men.¹¹

Prostate Cancer Screening Recommendations

In its most recent prostate cancer screening recommendations, the United States Preventive Services Task Force (USPSTF) concluded that it is indeterminate whether it is 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 to high certainty that the harms of screening for prostate cancer outweigh the benefits.¹² 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.¹³

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.¹⁴ 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.

⁶ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *United States Cancer Statistics (USCS)*, 2007, available at <http://apps.nccd.cdc.gov/uscs/toptencancers.aspx> (Last visited on February 2, 2011). See also fn. 3.

⁷ *Supra* fn. 3.

⁸ Florida Department of Health, Bureau of Epidemiology, *Prostate Cancer in Florida 2006*, available at http://www.doh.state.fl.us/disease_ctrl/epi/cancer/Prostate_06.pdf (Last visited on February 2, 2011).

⁹ Centers for Disease Control and Prevention, *Prostate Cancer, Fast Facts*, available at http://www.cdc.gov/cancer/prostate/basic_info/fast_facts.htm (Last visited on February 2, 2011).

¹⁰ *Supra* fn. 8.

¹¹ *Id.*

¹² U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force, *Screening for Prostate Cancer, Clinical Summary of U.S. Preventive Services Task Force Recommendation*, August 2008, available at <http://www.uspreventiveservicestaskforce.org/uspstf08/prostate/prostatesum.htm> (Last visited February 2, 2011).

¹³ *Id.*

¹⁴ American Cancer Society, *Prostate Cancer: Early Detection*, available at <http://www.cancer.org/cancer/prostatecancer/moreinformation/prostatecancerearlydetection/prostate-cancer-early-detection-acs-recommendations> (Last visited on February 2, 2011).

The Department of Health

Section 20.43, F.S., creates the DOH. The DOH 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; and by ensuring essential health care and an environment which enhances the health of the individual and the community.¹⁵ The State Surgeon General is the State Health Officer and the head of the DOH.

The primary focus of the DOH'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.¹⁶ The Men's Health Initiative provides prostate cancer awareness, screening, and risk factor information.

Prostate Cancer Awareness Program

In 2004, the Legislature created the Program within the DOH.¹⁷ 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.¹⁸ The DOH is required to coordinate its Program with the efforts of the Florida Public Health Institute, Inc. (Institute).¹⁹

The Prostate Cancer Advisory Committee (Committee) is created under s. 381.911, F.S., to assist the DOH and the Institute in implementing the 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.

¹⁵ Section 381.001, F.S.

¹⁶ The Department of Health, *Men's Health Initiative*, available at <http://www.doh.state.fl.us/family/menshealth/index.html> (Last visited on February 2, 2011).

¹⁷ Section 14, ch. 2004-2, L.O.F.

¹⁸ Section 381.911, F.S.

¹⁹ The Florida Public Health Institute, acting as a neutral convener, works with various local, state and national leaders to develop public-private partnerships that provide recommendations and solutions to health-related matters for the citizens of the state of Florida and the national community. Its mission is to "...advance the knowledge and practice of public health to promote, protect and improve the health of all." The Institute advances improvements in health through community education; health advocacy; health workforce training; and assessment, research and evaluation. See Florida Public Health Institute, *FPHI History*, available at <http://www.flphi.org/ABOUTUS/FPHIHistory/tabid/164/Default.aspx> (Last visited on February 4, 2011).

In 2004, the Legislature provided funding for the DOH for prostate cancer education and the DOH convened a meeting of the Committee.²⁰ No additional funds have been appropriated for the Program and the Committee has not met since 2004.

The Comprehensive Cancer Control Program

The Comprehensive Cancer Control Program, housed under the Bureau of Chronic Disease Prevention and Health Promotion in the DOH, is funded through a cooperative agreement with the Centers for Disease Control and Prevention. The program focuses on colorectal, lung, ovarian, prostate, and skin cancers. The main objective of the cooperative agreement is to reduce the cancer burden through a collaborative effort with public and private partners throughout Florida. This is accomplished by working with the existing governor-appointed Cancer Control Research Advisory Board (C-CRAB) and a myriad of statewide cancer stakeholders including the National Cancer Institute's Cancer Information Services, the American Cancer Society, and Florida Comprehensive Cancer Control Initiative, among others.²¹

University of Florida Prostate Disease Center

The UFPDC was established in 2009 within the University of Florida's Urology Department. The UFPDC is an inter-disciplinary, statewide research and education center that facilitates the development of state-of-the-art diagnostic tools and advanced treatment methods for prostate disease. It investigates prostate disease on a preclinical and clinical level, pushing forth new medical knowledge, setting new benchmarks for standards of care and advancing new principles for future biomedical training. The UFPDC uses the expertise of scientists and clinicians in urology, cellular and molecular biology, physics, immunology, pharmacology, socio-behavioral sciences, functional genomics, nursing, radiation oncology, medical oncology, cancer endocrinology, and epidemiology to improve the lives of those diagnosed with prostate cancer.²²

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.²³ The C-CRAB is housed at, and administratively supported by the H. Lee Moffitt Cancer Center and Research Institute, but operates as an independent group.²⁴ The C-CRAB consists of 34 members, who meet at least twice a year.²⁵ The C-CRAB annually approves the Florida Cancer Plan, which is a program for cancer control and research. Additional responsibilities of the C-CRAB include:

²⁰ Ch. 2004-268, Laws of Florida.

²¹ Florida Department of Health, *Florida Cancer Plan*, available at <http://www.doh.state.fl.us/family/cancer/plan/> (Last visited on February 3, 2011).

²² University of Florida, Department of Urology, *News and Events*, available at http://urology.ufl.edu/news_events.php (Last visited on February 3, 2011).

²³ Section 1004.435(4)(h), F.S.

²⁴ Cancer Control Research Advisory Council, *2010 Annual Report*. A copy of the report is on file with the Senate Health Regulation Committee.

²⁵ *Id.*

- 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;
- If funded by the Legislature, 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.

Statewide Cancer Registry

Section 385.202, F.S., requires each hospital or other licensed facility to report to the DOH information that indicates diagnosis, stage of disease, medical history, laboratory data, tissue diagnosis, and radiation, surgical, or other methods of diagnosis or treatment for each cancer diagnosed or treated by that facility. The DOH, or a medical organization pursuant to a contract with the DOH, is required to maintain and make available for research such information in a statewide cancer registry.

Information in the statewide cancer registry that discloses or could lead to the disclosure of the identity of any person whose condition or treatment has been reported and studied is confidential and exempt from Florida's public records laws. However, such information may be disclosed with the consent of the affected person; if such information is to be used for epidemiologic investigation and monitoring; or if the information is used by any other governmental agency or contractual designee for medical or scientific research.

Advisory Councils

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.

III. Effect of Proposed Changes:

The CS amends s. 381.911, F.S., to modify the purpose of the Prostate Cancer Awareness Program (Program). The Program's purpose under the CS is to promote prostate cancer awareness; communicate the advantages of early detection; report of recent progress in prostate cancer research and the availability of clinical trials; minimize health disparities; communicate best-practice principles to physicians treating prostate cancer patients; and establish a communication platform for patients and their advocates.

The CS authorizes the University of Florida Prostate Disease Center (UFPDC) to implement the Program by working with other agencies, organizations, and institutions to create a systematic approach to increase community education and public awareness about prostate cancer.

The CS repeals responsibilities of the Florida Public Health Institute to participate in implementation of the Program.

The CS repeals the Prostate Cancer Advisory Committee, whose members were appointed by the State Surgeon General and establishes a UFPDC Prostate Cancer Advisory Council (Advisory Council). The Advisory Council is created to develop and implement strategies to improve outreach and education about prostate cancer.

The CS specifies that the Executive Director of the UFPDC shall appoint, in consultation with the DOH's Comprehensive Cancer Control Program and the State Surgeon General, a geographically and institutionally diverse advisory council. The Advisory Council is to consist of two persons from prostate cancer survivor groups or other cancer-related advocacy groups; four persons, including two physicians, a scientist, and the Executive Director of the University of Florida Prostate Disease Center or a designee; and three persons who are engaged in cancer-related medical specialty practice. Advisory Council members are to serve 4-year terms, but the initial members will have staggered terms. The Advisory Council is to meet annually and at the call of the Executive Director or by a majority vote of the members.

The duties of the Advisory Council include:

- Presenting prostate-cancer-related policy recommendations to the DOH and other governmental entities;
- Verifying the accuracy of prostate cancer information disseminated to the public;
- Developing effective communication channels among all private and public entities in the state involved in prostate cancer education, research, treatment, and patient advocacy;
- Planning, developing, and implementing activities designed to heighten awareness and educate residents of the state, especially those in underserved areas, regarding the importance of prostate cancer awareness;
- Disseminating information about recent progress in prostate cancer research and the availability of clinical trials;
- Minimizing health disparities through outreach and education;

- Communicating best-practices principles to physicians involved in the care of patients with prostate cancer;
- Establishing a communication platform for patients and their advocates;
- Soliciting grants and funding to conduct an annual prostate cancer symposium; and
- Submitting and presenting an annual report to the Governor, Legislature, and State Surgeon General by January 15, 2012, and each year thereafter, to recommend legislative changes to decrease the incidence of prostate cancer, decrease disparities among persons diagnosed with prostate cancer, and promote increased community education and awareness of prostate cancer.

The effective date of the CS is July 1, 2011.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this CS 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 CS 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 CS 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 adopt best-practices recommended by the Advisory Council, which may include additional prostate cancer screenings of patients.

C. Government Sector Impact:

The costs that might be incurred by the UFPDC through implementation of the Program are indeterminate.²⁶

²⁶ Professional committee staff of the Health Regulation Committee has requested an analysis of SB 414, including a fiscal analysis, from the Board of Governors.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The CS, on lines 120 through 121, requires the Advisory Council to “verify the accuracy of prostate cancer information disseminated to the public.” It is important to note that there may be vast amounts of information related to prostate cancer disseminated to the public over the Internet. If the intent is to require the Advisory Council to verify the accuracy of specific types of documents, such as research studies or medical journals, this language may need clarification.

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 February 8, 2011:

The CS differs from the bill in that it:

- Replaces the task force with an advisory council.
- Deletes a redundant reference to the Florida Cancer Control Program.
- Deletes the requirements for the task force to develop and maintain a prostate cancer registry and tissue bank.
- Makes a technical correction in the “whereas” clause.

- B. **Amendments:**

None.