

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Date: November 3, 1997 Revised: _____

Subject: Prostate Cancer

	<u>Analyst</u>	<u>Staff Director</u>	<u>Reference</u>	<u>Action</u>
1.	<u>Williams</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/CS</u>
2.	_____	_____	<u>WM</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

I. Summary:

Committee Substitute for Senate Bill 94 directs the Florida Cancer Control and Research Advisory Council, commonly referred to as the C-CRAB, at the H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida, to the extent funds are specifically appropriated, to develop or purchase a standardized, easy-to-understand, written statement regarding prostate cancer treatment alternatives, including the relative advantages, disadvantages, and associated risks of treatment. (A similar requirement currently exists regarding breast cancer treatment alternatives.) The pamphlet or booklet is to be made available to treating physicians, be updated periodically, and targeted to prostate cancer patients and those men considering prostate cancer screening. The C-CRAB is directed to develop and implement an education program centered around the distribution of the material, and the early detection and treatment of prostate cancer. The bill provides for a \$50,000 general revenue appropriation for this purpose for fiscal year 1998-99.

The bill amends s. 240.5121(4)(m), F.S.

II. Present Situation:

Cancer of the prostate, a common form of cancer, is a disease in which cancer (malignant) cells are found in the prostate. The prostate is a walnut-sized gland that forms part of the male reproductive system. The gland is composed of two lobes, or regions, enclosed by an outer layer of tissue. The prostate is located in front of the rectum and just below the bladder, where urine is stored. The prostate also surrounds the urethra, the canal through which urine passes out of the body. While scientists do not know all of the prostate's functions, they do know that one of the gland's main roles is to squeeze fluid into the urethra as sperm move through during sexual

climax. The prostate makes fluid that becomes part of the semen, the white fluid that contains sperm.

With 41,800 prostate cancer deaths a year in the United States, prostate cancer is the most common type of cancer found in men and the second most common cause of cancer death among men, after lung cancer. The American Cancer Society projects that at least 209,000 new cases of prostate cancer will be discovered this year in the United States. While some people feel this number is too high, experts say 40-50 percent of all men over age 50 will develop prostate tumors during their lifetimes. The American Cancer Society estimates that there will be 16,000 new cases of prostate cancer diagnosed in Florida in 1997, and 3,200 deaths in Florida directly attributable to prostate cancer, which is by number, second to lung cancer deaths in cancer deaths to men.

Little is known about the causes of prostate cancer. Research indicates that risk factors include age (risk increases after age 50), a family history of prostate cancer, race (African-American men are at up to 40 percent higher risk of developing prostate cancer than men of other races), and eating a high-fat diet. Typically, prostate cancers take four years or more to double in size, compared, for example, to breast cancers, which can double in size in less than three months. Adding to the difficulties associated with prostate cancer is that no one can distinguish at present between those prostate cancers which will cause no trouble in a man's lifetime and those which will spread and should be treated.

Prostate cancer can be detected by a digital rectal examination (DRE) and the prostate-specific antigen (PSA) blood test. Transrectal ultrasound and biopsies may be needed to determine the cause for an elevated PSA. Guidelines for routine screening of healthy men vary. The American Cancer Society and the American Urological Association recommend that a PSA test and DRE should be offered annually, beginning at age 50, to men who have at least a 10-year life expectancy, and to younger men who are at high risk. An abnormal PSA test result is above 4.0 ng/ml. The American Cancer Society also recommends that patients should be told by their physicians that a PSA level of 4.0 ng/ml or less does not guarantee that prostate cancer is not present. The National Cancer Institute and the U.S. Preventive health Task Force recommend an annual DRE for men over 40, but they do not recommend routine PSA tests for men without symptoms.

The controversy surrounding PSA screening is based on several issues: the high rate of "false positive" results and unnecessary biopsies; the test's inability to distinguish between tumors that will not grow and cause problems and those that may be fatal; whether screening reduces mortality and extends life; and the complications of treatment.

A variety of treatment options, including surgical removal of the prostate, cryosurgery, hormone therapy, various kinds of radiation, and, for some, watchful waiting, are used to treat prostate cancer. There are few long-term studies available to measure the relative success of these approaches. Although progress has been made in improving many of the techniques, some treatment options may result in long-term or permanent incontinence and impotence. Given these side effects, physicians and patients reviewing treatment options must consider the patient's

general health, age, expected life span, personal preferences, anticipated effects of treatment, as well as the stage and aggressiveness of the disease.

Despite the different recommendations for screening, there is agreement about the need for public information about prostate cancer. Persons who could benefit from screening need to know of the benefit. Persons to whom screening is offered may know very little about the choices they could make, if the screening result is positive.

Part V of chapter 240, F.S., provides for specific programs and institutions related to postsecondary education. Among these, s. 240.5121, F.S., is the "Cancer Control and Research Act," which includes as subsection (4) the creation and functions of the C-CRAB. Among the current duties is the requirement in paragraph (m) that C-CRAB prepare and distribute a patient education pamphlet that describes breast cancer treatment options. With specific funding from the Legislature, C-CRAB developed a pamphlet in 1996. It includes a brief description of breast cancer, including stage of disease, and the main types of treatment: surgery (lumpectomy, mastectomy and reconstruction), radiation therapy, chemotherapy, and hormone therapy. It also briefly describes clinical trials, bone marrow transplantation, and other related issues such as nutrition, rehabilitation, support groups, and follow-up care. A comprehensive list of resources for further information is also included. The statute also directs C-CRAB to develop and implement an education program centered around the distribution of the material, and the early detection and treatment of breast cancer, and to make the material available to treating physicians.

Recognizing the importance of prostate cancer in Florida, the C-CRAB has included a prostate cancer section in the 1998-1999 Florida Cancer Plan which is scheduled for final approval at C-CRAB's November 3, 1997, meeting. The plan's goal for prostate cancer is, "to increase awareness about prostate cancer, and options for screening and treatment." Specific recommendations are:

- State funding should be appropriated for an educational campaign, including a pamphlet for men considering screening, that explains the risk factors, screening recommendations, and treatment options for prostate cancer. Emphasis should be given to men at high risk for getting and dying from prostate cancer.
- C-CRAB should convene a Technical Advisory Group to continually monitor information about prostate cancer screening, and to develop recommendations to the Agency for Health Care Administration, the Department of Health, and the Legislature regarding insurance coverage for prostate cancer screening tests.
- Continuing medical education and medical school curricula should include information on prostate cancer, its risks factors, recommendations for early detection, and treatment options.

At this time, Florida has no federal- or state-funded programs relating specifically to prostate cancer.

III. Effect of Proposed Changes:

Section 1. Amends s. 240.5121(4)(m), F.S., relating to the duties and functions of the C-CRAB, to direct the C-CRAB, to the extent funds are specifically appropriated, to develop or purchase a standardized, easy-to-understand, written statement regarding prostate cancer treatment alternatives, including the relative advantages, disadvantages, and associated risks of treatment. The pamphlet or booklet is to be made available to treating physicians, updated periodically, and targeted to prostate cancer patients and those men considering prostate cancer screening. The C-CRAB is directed to develop and implement an education program centered around the distribution of the pamphlet and the early detection and treatment of prostate cancer.

Section 2. Provides for a \$50,000 general revenue appropriation for this purpose for fiscal year 1998-99.

Section 3. Provides for a July 1, 1998, effective date.

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 Section 24(a) of Article 1 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, Section 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

To the extent that prostate treatment awareness increases, the public will be better informed as to treatment options and considerations. More informed choices regarding prostate cancer screening and treatment will have an inestimable, positive impact on the public.

C. Government Sector Impact:

The bill provides a \$50,000 general revenue appropriation to the Moffitt Cancer Center for the development or purchase of the pamphlet or brochure and to distribute the pamphlet, and to develop and implement the education program that includes distribution of the pamphlet.

VI. Technical Deficiencies:

None.

VII. Related Issues:

In reviewing an identical bill, Senate Bill 1540, during the 1997 session, the staff of the C-CRAB expressed a concern that, while the \$50,000 appropriation will likely be adequate to defray original development costs, additional subsequent funding will likely be necessary to provide the ongoing production and distribution of the material. This is based on C-CRAB's experience with the comparable activity related to breast cancer treatment awareness.

As a compliment to the provisions in s. 240.5121(4)(m), F.S., relating to breast cancer treatment alternatives, ss. 458.324 and 459.0125, F.S. require physicians respectively licensed under these chapters to inform patients diagnosed with breast cancer about available treatment options. A similar requirement in these licensure provisions for prostate cancer treatment alternatives might assist with this educational effort.

According to the September 1997 issue of the C-CRAB Newsletter, several states adopted prostate cancer-related legislation in 1997. Two states recently enacted legislation similar to Senate Bill 94. California requires their state health department to develop an educational pamphlet on treatment options. The Texas state health department is required to develop and implement a program that provides information to the public about prostate cancer causes, early detection, and treatment options. In addition, seven states (Alaska, Colorado, Delaware, Georgia, Minnesota, New Jersey, and North Carolina) enacted laws requiring insurers to cover prostate-specific antigen (PSA) tests and digital rectal examinations.

VIII. Amendments:

None.