

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 620

INTRODUCER: Health Regulation Committee

SUBJECT: Biomedical Research Programs

DATE: January 21, 2010 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	Fav/CS
2.			HE	
3.			WPSC	
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 bill saves from repeal the James and Esther King Biomedical Research Program (King Program) and the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program). Unless reenacted by the Legislature, authorization for the King Program and the Bankhead-Coley Program will expire on January 1, 2011. The bill also:

- Establishes a 4-year staggered term of membership for the Biomedical Research Advisory Council and increases the number of members on the council;
- Requires the Department of Health (DOH) to adopt rules to administer these research programs;
- Specifies a recurring source of funding for the King Program and the Bankhead-Coley Program and allocates \$25 million annually for each program;
- Expands the purposes for which funds in both programs may be used;
- Authorizes the DOH to receive restricted or unrestricted gifts to further the goals of the programs;
- Repeals obsolete provisions and other provisions pertaining to the Legislature’s review and reenactment of these two programs;
- Repeals the Florida Cancer Council;

- Emphasizes cancer clinical trials projects and goals in the Bankhead-Coley Program;
- Creates the Florida Comprehensive Cancer Control Act;
- Establishes the Florida Cancer Control and Resource Advisory Council to replace the Cancer Control and Research Advisory Council, which is repealed; and
- Establishes the Florida Cancer Control Collaborative Program to support future cancer control initiatives.

This committee substitute substantially amends the following sections of the Florida Statutes: 215.5602, 381.922, 458.324, and 459.0125.

This committee substitute creates the following section of the Florida Statutes: 381.923.

This committee substitute repeals the following sections of the Florida Statutes: 381.92, 381.921, and 1004.435.

II. Present Situation:

The James and Esther King Biomedical Research Program

The Florida Legislature created the Florida Biomedical Research Program in 1999 within the DOH. The Florida Biomedical Research Program was renamed the James and Esther King Biomedical Research Program during Special Session B of the 2003 Legislature.

The purpose of the King Program is to provide an annual and perpetual source of funding to support research initiatives that address the health problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.¹ The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
- Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers.
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The King Program offers competitive grants to researchers throughout Florida to fulfill its goals. Grant applications from any university or established research institute² in this state will be

¹ s. 215.5602, F.S.

² An established research institute is any Florida non-profit or foreign non-profit corporation covered under Ch. 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals, including veterans administration hospitals. See the Call for Grant Applications 2009-2010, page 7, available at: <http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf> (Last visited on January 6, 2010).

considered for biomedical research funding under the King Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.³

The State Surgeon General, after consultation with the Biomedical Research Advisory Council (the Advisory Council), is authorized to award grants and fellowships on the basis of scientific merit⁴ within the following three categories:

- Investigator-initiated research grants, which are designed to initiate research that can be subsequently funded from a national agency,
- Institutional research grants, which are intended to foster the development of new and promising research investigators so that they can undertake more independent research that would be competitive for national research funding as well as to attract talented researchers to Florida institutions, and
- Predoctoral and postdoctoral research fellowships.⁵

The William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program

The Bankhead-Coley Program was created in 2006 by the Florida Legislature within the DOH.⁶ The purpose of the Bankhead-Coley Program is to advance progress toward cures for cancer through grants awarded for cancer research.

The research funded under the Bankhead-Coley Program is intended to emphasize the goals of the Florida Cancer Council⁷ as those goals support the advancement of cures for cancer. The Florida Cancer Council was established in 2004 within the DOH for the purpose of making the state a center of excellence for cancer research. The duties of the Florida Cancer Council include:

- Efforts to significantly expand cancer research capacity in the state by:
 - Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
 - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
 - Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
 - Encouraging the employment of bioinformatics⁸ in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;

³ Grant award recipients have included the following institutions or investigators associated with these institutions: University of Miami (UM), University of Florida (UF), H. Lee Moffitt Cancer Center & Research Institute (Moffitt Cancer Center), University of Central Florida (UCF), M.D. Anderson Cancer Center, University of South Florida (USF), Florida State University (FSU), Roskamp Institute, Mayo Clinic, Florida Atlantic University (FAU), The Scripps Research Institute, Bay Pines VA Healthcare System, Florida Institute of Technology, and Nemours Children’s Clinic.

⁴ See the Grant Application and Processing section of Senate Interim Report 2010-219 for more information about assessing scientific merit.

⁵ The DOH staff indicated that funding constraints have limited awarding fellowships. However, it is anticipated that fellowships may be available in the near future as a result of the infusion of funding to the King Program.

⁶ s. 381.922, F.S., (Ch. 2006-182, L.O.F.).

⁷ See ss. 381.92 and 381.921, F.S.

⁸ Bioinformatics includes using computers to collect and analyze biochemical and biological information, especially related to molecular genetics and genomics. See <<http://www.merriam-webster.com/dictionary>> (Last visited on January 6, 2010).

- Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
- Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research;
- Efforts to improve both research and treatment through greater participation in clinical trials networks by:
 - Identifying ways to increase adult enrollment in cancer clinical trials;
 - Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
 - Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
 - Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks; and
- Efforts to reduce the impact of cancer on disparate groups by:
 - Identifying those cancers that disproportionately impact certain demographic groups; and
 - Building collaborations designed to reduce health disparities as they relate to cancer.

Applications for funding cancer research from any university or established research institute in the state will be considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.⁹ The State Surgeon General, after consultation with the Advisory Council, is authorized to award grants and fellowships on the basis of scientific merit¹⁰ within the following three categories:

- Investigator-initiated research grants,
- Institutional research grants, and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

Program Funding

Initially, the King Program was funded with income from \$150 million of principal in the Lawton Chiles Endowment Fund.¹¹ In 2004, the Legislature appropriated additional funding, through a distribution from alcoholic beverage surcharge taxes. In 2006, the Legislature substituted a six million dollar annual appropriation commitment from the General Revenue Fund to fund the Biomedical Research Trust Fund within the DOH for purposes of the King Program.¹² However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the King Program was reduced to \$4.5 million.¹³ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge

⁹ Grant award recipients have included the following institutions or investigators associated with these institutions: UM, UF, Moffitt Cancer Center, Florida International University, FAU, USF, M.D. Anderson Cancer Center, FSU, Mayo Clinic, Florida Institute of Technology, UCF, Florida Hospital Cancer Institute, and The Scripps Research Institute.

¹⁰ *Ibid* 4.

¹¹ s. 215.5601, F.S. The Lawton Chiles Endowment Fund's principal originated from a portion of the state settlement received from its lawsuit with tobacco companies.

¹² Ch. 2006-182, Laws of Florida (L.O.F.).

¹³ Ch. 2009-5, L.O.F.

enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the King Program for the 2009-2010 fiscal year.¹⁴ This is in addition to approximately \$3.5 to \$4.9 million in interest earnings on the \$150 million reserved in the Lawton Chiles Endowment Fund for the King Program.¹⁵ Of the funds appropriated for the King Program, up to \$250,000 per year is designated to operate the Florida Center for Universal Research to Eradicate Disease.¹⁶

The Bankhead-Coley Program was established with a commitment for an appropriation of \$9 million per year from the General Revenue Fund.¹⁷ However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program was reduced to \$6.75 million.¹⁸ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the Bankhead-Coley Program.¹⁹

Chapter 2009-58, Laws of Florida, provided that 5 percent of the revenue deposited into the Health Care Trust Fund pursuant to s. 210.011(9), F.S., related to the cigarette surcharge and s. 210.276(7), F.S., related to the surcharge on tobacco products, are to be reserved for research of tobacco-related or cancer-related illnesses. The sum of the revenue reserved, however, may not exceed \$50 million in any fiscal year. The Legislature did not specify an amount to be appropriated annually, after the 2009-2010 fiscal year, for the King Program or the Bankhead-Coley Program from these reserves.

Any cash balance in the Biomedical Research Trust Fund at the end of a fiscal year remains in the trust fund to be available for carrying out the purposes of the trust fund. In addition, any balance of an appropriation from the Biomedical Research Trust Fund which has not been disbursed, but which is obligated, may be used for up to three years from the effective date of the original appropriation.

Biomedical Research Advisory Council²⁰ and Peer Review Panel²¹

The purpose of the Advisory Council is to advise the State Surgeon General as to the direction and scope of the King Program. The Advisory Council is also required to consult with the State Surgeon General concerning grant awards for cancer research through the Bankhead-Coley

¹⁴ Ch. 2009-58, L.O.F.

¹⁵ DOH Bill Analysis, Economic Statement and Fiscal Note for SB 620, dated December 14, 2009, on file in the Senate Health Regulation Committee.

¹⁶ The purpose of the Florida Center for Universal Research to Eradicate Disease is to coordinate, improve, expand, and monitor all biomedical research programs within the state; facilitate funding opportunities; and foster improved technology transfer or research findings into clinical trials and widespread public use. See s. 381.855, F.S.

¹⁷ s. 381.922(5), F.S.

¹⁸ Ch. 2009-5, L.O.F.

¹⁹ Ch. 2009-58, L.O.F.

²⁰ s. 215.5602(3), F.S.

²¹ s. 215.5602(6) and (7), and s. 381.922(3)(b), F.S.

Program.²² Currently there are 11 members on the Advisory Council, authorized to serve two consecutive 3-year terms.

In order to ensure that proposals for research funding within the King Program and the Bankhead-Coley Program are appropriate and evaluated fairly on the basis of scientific merit, a peer review panel of independent, scientifically qualified individuals is appointed to review the scientific content of each proposal to establish a [scientific]²³ priority score.²⁴ To eliminate conflicts of interest, peer reviewers come from outside the state of Florida. Reviewers are experts in their fields from universities, government agencies, and private industry who are matched according to application topic and area of expertise. The priority scores must be considered by the Advisory Council in determining which proposals will be recommended for funding to the State Surgeon General.

Meetings of the Advisory Council and the peer review panel are subject to ch. 119, F.S., relating to public records; s. 286.011, F.S., relating to public meetings; and s. 24, Article I of the State Constitution relating to access to public meetings and records.

Program Administration and Grant Management

The Office of Public Health Research within the DOH manages both the King Program and the Bankhead-Coley Program with support from the Advisory Council and Lytmos Group, LLC (Lytmos), pursuant to contract.

The law authorizes, but does not require, the DOH, after consultation with the Advisory Council, to adopt rules as necessary to implement these programs.²⁵ The DOH has not adopted rules to implement these programs. Instead, the DOH publishes, on its website, the procedures for implementing these two programs.²⁶ The Joint Administrative Procedures Committee recently contacted the DOH concerning unadopted rulemaking.²⁷

The *GrantEase*TM online system is used by grantees to access grant information and submit progress reports, invoices, financial reports, and change requests during the life of the grant. At least once during the grant period, the grantee is subjected to on-site monitoring for both scientific and administrative purposes.

Mandatory Review

The 2006 Legislature required a review of the performance, outcomes, and financial management of the King Program and the Bankhead-Coley Program during the 2010 Regular Session of the Legislature. The 2010 Legislature will determine the most appropriate funding

²² s. 381.922(3)(a), F.S. However, s. 215.5602(11), F.S., contains an inconsistency with respect to the responsibility of the Advisory Council concerning awarding grants for cancer research.

²³ The King Program requires a *scientific* priority score in s. 215.5602(6), F.S. The Bankhead-Coley Program requires a priority score in s. 381.922(3)(b), F.S.

²⁴ A Bridge Grant application is ranked solely by the priority score or percentile assigned to its qualifying federal proposal in an eligible federal review process.

²⁵ s. 215.5602(9), F.S.

²⁶ See: <<http://www.doh.state.fl.us/ExecStaff/biomed/ophrsitemap.html>>, (Last visited on January 6, 2010).

²⁷ Correspondence from the Joint Administrative Procedures Committee to the State Surgeon General dated August 6, 2009.

source and means of funding these programs. The statutes establishing these two programs expire January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation performed the mandatory review of the King Program and the Bankhead-Coley Program as provided in ss. 215.5602 and 381.922, F.S. The recommendations in the resulting report²⁸ are that the Legislature re-enact the King Program and the Bankhead-Coley Program and further refine the statutory provisions governing these two programs. Portions of this committee substitute implement the professional staff's recommendations in accordance with the committee's direction.

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 with respect to cancer control and research in this state. The C-CRAB consists of 34 members. Annually the C-CRAB approves the Florida Cancer Plan, which is a program for cancer control and research that must be consistent with the State Health Plan and integrated and coordinated with existing programs in this state. 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.

III. Effect of Proposed Changes:

Section 1. Amends s. 215.5602, F.S., related to the King Program to:

- Eliminate reference to funding the King Program with certain proceeds of the Lawton Chiles Endowment Fund. The income earned on the reserve in the Lawton Chiles Endowment Fund

²⁸ Biomedical Research Programs – Performance, Outcomes, and Financial Management, dated September 2009, available at: <http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-219hr.pdf>, (Last visited on January 6, 2010).

that is set aside for funding biomedical research activities in the King Program in s. 215.5601(3)(d), remains available for appropriation;

- Dedicate 5 percent of the revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds for the King Program and the Bankhead-Coley Program annually and remove the limitation that the 5 percent cannot exceed \$50 million annually;
- Allocate \$25 million each to the King Program and the Bankhead-Coley Program, annually;
- Increase funding from the King Program for the operating costs of the Florida Center for Universal Research to Eradicate Disease to \$500,000 and provide clarification concerning the exclusive use of the appropriations to the King Program;
- Authorize grant awards for training;
- Authorize up to one-third of the annual allocation for the recruitment of cancer, heart, or lung researchers and research teams to institutions in this state; operational start-up grants for newly recruited researchers and teams; and equipment expenditures related to expansion of cancer, heart, or lung research and treatment capacity in this state;
- Reduce the percentage of annual funding that is available for administrative expenses related to the King Program from 15 percent to 7.5 percent;
- Require the DOH to adopt rules to administer the programs and authorize those rule to enable a process to award grants timely;
- Change the length of membership on the Biomedical Research Advisory Council from 3 years to 4 years; establish a system to stagger membership on the council; and add two members to the Advisory Council including the chief executive officer of Enterprise Florida, or a designee and the chief executive officer of BioFlorida, or a designee;
- Authorize the DOH to deposit restricted or unrestricted gifts into the Biomedical Research Trust Fund for purposes of the King Program; and
- Eliminate the 2009-2010 fiscal year appropriation, direction to the Division of Statutory Revision concerning the statutory citation of this section, the required Legislative review of the program, and the provision concerning expiration of the section, all of which will become obsolete upon enactment of this bill.

Section 2. Repeals s. 381.92, F.S., related to the Florida Cancer Council.

Section 3. Repeals s. 381.921, F.S., related to the mission and duties of the Florida Cancer Council. The goals of the Florida Cancer Council are moved into the Bankhead-Coley Program.

Section 4. Amends s. 381.922, F.S., related to the Bankhead-Coley Program to:

- Expand the purpose of the program to include expanding cancer research and treatment capacity in this state;
- Specify the goals of the program are designed to foster dramatic improvement in cancer research capacity in this state, improve research and treatment through greater participation in clinical trial networks, and reduce the impact of cancer on disparate groups. These goals were previously cross-referenced to the Florida Cancer Council, which is repealed in this committee substitute;
- Add another factor to be given preference when evaluating grant proposals, which is the transfer of knowledge gained from research into the practice of community practitioners;
- Authorize grant awards for training, predoctoral and postdoctoral research fellowships, and clinical trial project grants that match patients with clinical trials opportunities;

- Authorize up to one-third of the annual allocation for the recruitment of cancer researchers and research teams to institutions in this state; operational start-up grants for newly recruited researchers and teams; and equipment expenditures related to expansion of cancer research and treatment capacity in this state;
- Change the due date to February 1 of each year for the DOH to report on the progress towards the program's mission and any applicable recommendations;
- Designate the 5 percent of the revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds for the King Program and the Bankhead-Coley Program as a funding source for the Bankhead-Coley Program and allocate \$25 million of this amount annually to the Bankhead-Coley Program;
- Authorize the DOH to deposit restricted or unrestricted gifts into the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program and allocate \$25 million annually to the Bankhead-Coley Program;
- Reduce the percentage of annual funding that is available for administrative expenses related to the Bankhead-Coley Program from 15 percent to 7.5 percent;
- Authorize the DOH to deposit restricted or unrestricted gifts into the Biomedical Research Trust Fund for purposes of the Bankhead-Coley Program; and
- Eliminate the 2009-2010 fiscal year appropriation, direction to the Division of Statutory Revision concerning the statutory citation of this section, the required Legislative review of the program, and the provision concerning expiration of the section, all of which will become obsolete upon enactment of this bill.

Section 5. Creates s. 381.923, F.S., to be cited as the "Florida Comprehensive Cancer Control Act" (The Cancer Control Act) The expressed Legislative intent in the committee substitute focuses on education and awareness concerning advances in scientific knowledge related to the control of cancer to reduce the cancer burden for the residents of this state. The committee substitutes defines the terms "cancer," "council," "department," "plan," "program," and "qualified nonprofit association" for purposes of the Cancer Control Act.

The Florida Cancer Control and Resource Advisory Council (The Council) is created within the H. Lee Moffitt Cancer Center and Research Institute, Inc., the Florida Cancer Control and Resource Advisory Council. Each members of The Council must be a resident of this state. The composition of the 42 member council includes:

- Three members representing the general public that are appointed by the Governor;
- A member of the Senate, appointed by the President of the Senate;
- A member of the House of Representatives, appointed by the Speaker of the House of Representatives;
- A representative appointed by:
 - H. Lee Moffitt Cancer Center and Research Institute, Inc.;
 - University of Florida Shands Cancer Center;
 - University of Miami Sylvester Comprehensive Cancer Center;
 - Mayo Clinic, Florida;
 - M.D. Anderson Cancer Center, Florida;
 - American Cancer Society, Florida Division;
 - American Association for Retired Persons;
 - Department of Health;

- Department of Education;
- Florida Tumor Registrars Association;
- Florida Cancer Data System;
- Florida Society of Oncology Social Workers;
- Florida Oncology Nurses Society;
- Florida Society of Clinical Oncology;
- Florida Association of Pediatric Tumor Programs, Inc;
- Cancer Information Service;
- Florida Medical Association;
- Florida Hospital Association;
- Florida Nursing Association;
- Florida Dental Association;
- Florida Osteopathic Association;
- University of Florida College of Medicine;
- University of Miami College of Medicine;
- University of South Florida College of Medicine;
- Florida State University College of Medicine;
- University of Central Florida College of Medicine;
- Nova Southeastern College of Osteopathic Medicine;
- University of Central Florida College of Medicine;
- Florida International University College of Medicine;
- Lake Erie School of Osteopathic Medicine;
- Biomedical Research Advisory Council;
- Center for Universal Research to Eradicate Disease; and
- Each of the regional Cancer Control Collaboratives. Currently there are five regional Cancer Control Collaboratives.

The committee substitute designates membership of an executive committee for The Council. The Council must meet at least semiannually and may prescribe, amend, and repeal bylaws governing The Council. Members of The Council are prohibited from participating in any discussion or decision to recommend an award or contract to any qualified nonprofit association or to any agency of this state or its political subdivision with which the member is also a member of the governing body, an employee, or has entered into a contractual arrangement.

The Council is required to:

- Advise the Governor, Legislature, State Surgeon General, or other policymakers with respect to cancer control and resources in this state;
- Approve a program for cancer control to be known as the “Florida Cancer Plan” and review it at least every two years;
- Recommend to the Governor, Legislature, State Surgeon General, or other policymakers an evidence-based plan for the prevention and early detection of cancer. The State Surgeon General and other state policymakers are required to consider this plan in developing department priorities and funding priorities and standards under ch. 395, F.S., relating to hospital licensing and regulation;
- Provide expertise and input in the content and development of the Florida Cancer Plan. Recommendations must include coordination and integration of other state plans concerned with cancer control;

- Advise the State Surgeon General on methods of enforcing and implementing laws that are concerned with cancer control; and
- Report any findings and recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by December 1 of each year.

The Council is authorized to:

- Form committees to address the following areas for action:
 - Cancer plan evaluation, including tumor registry, data retrieval systems, and epidemiology of cancer in the state and its relation to other areas;
 - Cancer prevention;
 - Cancer detection;
 - Cancer treatments;
 - Support services for cancer patients and caregivers;
 - Cancer education for laypersons and professionals; and
 - Other cancer-control-related topics; and
- Recommend to the State Surgeon General rulemaking to enable The Council to perform its duties and properly administer the Cancer Control Act.

The H. Lee Moffitt Cancer Center and Research Institute must house The Council and provide a full-time executive director and additional administrative support for the Council. This responsibility is funded with \$150,000 from the Bankhead-Coley Research Program.

The DOH is authorized to adopt rules necessary to administer the Cancer Control Act.

The Florida Cancer Plan is established within the DOH. The DOH is required to consult with The Council in developing the plan, prioritizing goals, and allocating resources.

The Cancer Control Collaborative Program (Collaborative Program) is established within the cancer program of the DOH. The Collaborative Program is responsible for overseeing and providing infrastructure for the state cancer collaborative network by implementing the Florida Cancer Plan's initiatives and facilitating the local development of solutions to cancer control needs. The DOH must appoint a cancer program director to be responsible for supervising the collaborative program and providing support to the regional cancer control collaboratives. This support must include, at a minimum, centralized organization, communications, information technology, shared resources, and cancer control expertise. The Collaborative Program must submit a report to The Council by October 15 of each year. The Council shall have input, consistent with the Florida Cancer Plan, into the prioritization of programs and proposed allocation of resources in the Collaborative Program. The Collaborative Program is also required to serve as the infrastructure for expansion or adaption as federal programs or other opportunities arise for future cancer control initiatives. The infrastructure for the local cancer control collaboratives is required, to the extent possible, to be designed to leverage federal funding opportunities.

Each regional cancer control collaborative must bring together local stakeholders, develop bylaws, identify priority cancer control needs of its region, and develop solutions to solve problems. The solutions must be consistent with the Florida Cancer Plan. Each regional cancer

control collaborative must meet at least semiannually and send representation to The Council meetings.

Section 6. Amends s. 458.324, F.S., related to information on treatment alternatives for breast cancer under the practice of medicine, to strike references to the C-CRAB and s. 1004.435, F.S., because that section of the Florida Statutes is repealed in section 8 of this committee substitute. The requirement for the practitioner to provide a written summary to the patient is retained. (See comment under Technical Deficiencies.) The Florida Cancer Control and Resource Advisory Council is established in this committee substitute to replace the C-CRAB.

Section 7. Amends s. 459.0125, F.S., related to information on treatment alternatives for breast cancer under the practice of osteopathy, to strike references to the C-CRAB and s. 1004.435, F.S., because that section of the Florida Statutes is repealed in section 8 of this committee substitute. The requirement for the practitioner to provide a written summary to the patient is retained. (See comment under Technical Deficiencies.) The Florida Cancer Control and Resource Advisory Council is established in this committee substitute to replace the C-CRAB.

Section 8. Repeals s. 1004.435, F.S., related to the Cancer Control and Research Act.

Section 9. Provides an effective date of July 1, 2010.

Other Potential Implications: Currently, 5 percent of revenue deposited into the Health Care Trust Fund from the cigarette and tobacco tax proceeds is reserved for research of tobacco-related or cancer-related illnesses. This bill dedicates the entire 5 percent for the King Program and the Bankhead-Coley Program, subject to annual appropriations.

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 the bill have no adverse 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:

Continuing these two programs benefits both the private sector and the government sector of the state. Specifically, the King Program is leveraging research funding in the state for improvement of tobacco-related health conditions, expanding the foundation of biomedical knowledge, improving the quality of the state's academic health centers, increasing the state's per capita funding for research, and stimulating the economy. The Bankhead-Coley Program is expanding cancer research capacity in this state, improving research and treatment through clinical trials, and undertaking activities to reduce the impact of cancer on disparate groups. Dedicating a funding source for these programs provides continuity and expresses a commitment to improving Florida's position as a viable participant in the research community.

C. Government Sector Impact:

Refer to the private sector impact above.

VI. Technical Deficiencies:

Section 1 of the bill on lines 301 – 308 amends s. 215.5602(12)(b), F.S., to dedicate 5 percent of certain revenue to the two programs and allocate \$25 million annually to the King Program and the Bankhead-Coley Program, each. Five percent of the revenue may exceed \$50 million or may be less than \$50 million. It is unclear what is contemplated if the 5 percent is less than the \$50 million allocated to the two programs.

Section 1 of the bill on lines 233-241 creates s. 215.5602(5)(c), F.S., to authorize the Advisory Council to recommend up to one-third of the allocation for the King Program for recruitment of researchers and research teams, operational start-up grants for newly recruited researchers and research teams; and equipment expenditures related to expansion of research and treatment capacity in this state. Although these categories might be funded through proposals for research funding, it is not apparent that they can be evaluated based on scientific content only.

Section 3 of the committee substitute on lines 352-359 amends s. 381.922(2), F.S., to authorize the Bankhead-Coley Program to provide grants for recruiting cancer researchers and research teams, operational start-up grants for newly recruited researchers and research teams, and equipment expenditures related to expansion of cancer research and treatment capacity in this state. Also, on lines 433-436 the bill creates a new s. 381.922(3)(b), F.S., to authorize the Advisory Council to recommend up to one-third of the allocation for the Bankhead-Coley Program for these same purposes. However, it does not appear that s. 381.922(3)(b), F.S., considers these as grants. In addition, although these categories might be funded through proposals for research funding, it is not apparent that they can be evaluated based on scientific content only.

Section 5 of the committee substitute establishes a council but does not specify term limits for the members and does not specify duties for the executive committee. In addition, lines 617-619 states, “A majority of members participating shall constitute a quorum ...” This is unclear.

Section 5. It is not clear whether the Florida Cancer Plan is a document that sets forth an approach to cancer control or a program. For example, Line 695 *establishes* the Florida Cancer Plan within the DOH and lines 636 – 640 refer to the Florida Cancer Plan as a program. But on line 640, The Council is required to review and approve the plan at least every 2 years; lines 650-651 require The Council to provide expertise and input in the content and development of the Florida Cancer Plan; lines 696 – 701 imply it is a document; and line 708 assigns responsibility to the Collaborative Program to implement the Florida Cancer Plan’s initiatives.

Section 5. Line 698 is part of a subsection specifying responsibilities of the DOH however, it requires The Council to approve the plan. This statement duplicates the requirement found on line 640.

Section 5. Lines 699-701 are also part of the subsection specifying responsibilities of the DOH but the language in these lines requires the Cancer Control Collaborative Program to prioritize programs and resources to reduce the burden of cancer in this state, consistent with the plan. This requirement should be moved under subsection (g) related to the Florida Cancer Control Collaborative Program.

Sections 6 and 7, prior to the amendment in this committee substitute refer to a written summary prepared by the C-CRAB in accordance with s. 1004.435(4)(m), F.S. The C-CRAB and s. 1004.435, F.S., are repealed. The Florida Cancer Control and Resource Advisory Council created in this committee substitute to replace the C-CRAB is not directed to prepare the written summary that is referred to in these sections. Either the provisions concerning the written summary should be removed from the practice acts or the responsibility to prepare and update the written summary should be provided in the statutes.

VII. Related Issues:

None.

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 Committee on January 19, 2010:

- Expands the number of members of the Advisory Council from 11 to 13 and identifies the entities to designate representatives to serve as members on the Advisory Council;
- Authorizes the King Program and the Bankhead-Coley Program to use funds to recruit researchers, provide for operational start-up grants for newly recruited researchers, purchase equipment, and provide training grants;

- Removes the \$50 million limitation on the 5 percent of revenue from the tobacco surcharge revenues dedicated to the King Program and the Bankhead-Coley Program;
- Allocates \$25 million on a recurring basis to the King Program and another \$25 million on a recurring basis to the Bankhead-Coley Program from the tobacco surcharge revenues;
- Reduces the percentage of funds allocated to the King Program and the Bankhead-Coley Program that might be used for administrative expenses;
- Increases the funding from \$250,000 to \$500,000 for the Florida Center for Universal Research to Eradicate Disease;
- Repeals the Florida Cancer Council;
- Authorizes the Bankhead-Coley Program to provide grants for cancer clinical trials projects;
- Revises the membership, mission, and duties of the C-CRAB, moves it from ch. 1004, F.S., to ch., 381, F.S., and renames it the Florida Cancer Control and Resource Advisory Council; and
- Establishes the Cancer Control Collaborative Program to support the regional cancer control collaboratives and future cancer control initiatives.

B. Amendments:

None.