

**HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS**

BILL #:	CS/CS/SB 1660	FINAL HOUSE FLOOR ACTION:	
SPONSOR(S):	Appropriations and Children, Families, and Elder Affairs, and Flores	117 Y's	0 N's
COMPANION BILLS:	None	GOVERNOR'S ACTION:	Approved

SUMMARY ANALYSIS

SB 1660 passed the House on May 3, 2013. The bill establishes the Cancer Center for Excellence Award (Award) to recognize hospitals, treatment centers, and other providers in Florida that demonstrate excellence in patient-centered, coordinated care for persons undergoing cancer treatment and therapy.

The bill requires the Florida Cancer Control and Research Advisory Council (CCRAB) and the Biomedical Research Advisory Council (BRAC) to form a joint committee to develop rigorous performance measures, a rating system, and a rating standard for earning an Award. The Department of Health (DOH) is required to develop an application form and annually conduct two application cycles for the Award. The bill requires the State Surgeon General to appoint a team of independent evaluators to assess Award applicants and provides reporting requirements related to identification of eligible Award applicants and the status of implementing the Award program. The bill allows awardees to use the Award designation in advertising and marketing for up to three years and provides that awardees are given preference in certain competitive solicitations.

The bill creates new reporting requirements for recipients of appropriations for biomedical and/or cancer research or related activities without existing statutory requirements and requires annual fiscal-year progress reporting describing the use of funds.

The bill creates an endowment program for cancer research chairs. DOH is required to award endowments in order to secure funding for at least seven years to attract an experienced and promising researcher who specializes in cancer-related research. The bill requires institutions that receive endowed chair funding to submit an annual report and provides that research chair endowments are contingent upon a specific appropriation in the General Appropriations Act (GAA).

The bill was approved by the Governor on May 20, 2013, ch. 2013-50, L.O.F., and became effective July 1, 2013.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Cancer is the leading cause of death in Florida. Florida has the second-highest number of new diagnosed cancer cases in the U.S., even though; it is the fourth-largest state in terms of population. However, there is only one National Cancer Institute - Designated Comprehensive Cancer Center in the state.¹ The National Cancer Institute designation is nationally recognized as a marker of high-quality in cancer care and research and is linked to higher federal funding for cancer treatment. Florida has fewer designated cancer centers than peer states. For example, New York has four centers, Texas has three, and California has ten.²

The Biomedical Research Program

The Florida Biomedical Research Program within DOH includes two distinct programs: the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

James and Esther King Biomedical Research Program

In 1999, the Legislature created the Florida Biomedical Research Program in DOH to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease.³ A component of the Biomedical Research Program was BRAC.⁴ BRAC was created to advise the State Surgeon General on the direction and scope of the state's biomedical research program, to include:

- Providing advice on program priorities, emphases, and overall program budget;
- Participating in periodic program evaluation;
- Assisting in developing guidelines for fairness, neutrality, principles of merit, and quality in the conduct of the program;
- Assisting in developing linkages to nonacademic entities such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials;
- Developing guidelines, criteria and standards for the solicitation, review, and award of research grants and fellowships; and
- Developing and providing oversight regarding mechanisms for disseminating research results.

BRAC is composed of 11 members:

- Two appointees by the Speaker of the House of Representatives from a professional medical organization or a comprehensive cardiovascular program with experience in biomedical research approved by the American College of Cardiology, and from a cancer program approved by the American College of Surgeons;
- Two appointees by the President of the Senate with expertise in behavioral or social research, and from a cancer program approved by the American College of Surgeons;
- Four appointees by the Governor with two members having expertise in biomedical research, one from a research university in Florida, and one representing the general public;

¹ H. Lee Moffitt Cancer Center is the only designated cancer center.

² Department of Health Bill Analysis for SB 1660 dated March 8, 2013, on file with the House Health Quality Subcommittee staff.

³ Chapter 99-167, L.O.F.

⁴ Section 215.5602(3), F.S.

- A representative of the American Cancer Society;
- A representative of the American Heart Association; and
- A representative of the American Lung Association.

At inception, the program was intended to be supported by funds from the Lawton Chiles Endowment Fund,⁵ but a specific appropriation amount was not statutorily indicated.⁶ Statute⁷ further stipulated that appropriated funds were to be used by the Florida Biomedical Research Program to provide grants and fellowships for research relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, and administrative expenditures.

In 2001, the Legislature amended the legislative purpose of the program, stating that the intent for the program was to provide an annual and perpetual source of funding to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.⁸ In 2003, the Florida Biomedical Research Program was renamed the “James and Esther King Biomedical Research Program (King Program).”⁹

The goals of the King 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.

Bankhead-Coley Program

In 2006, the Legislature created the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) within DOH. The purpose of the program was to advance progress towards cures for cancer through grant awards. The funds are distributed as grants to researchers seeking cures for cancer, with emphasis given to the efforts that significantly expand cancer research capacity in the state.¹⁰

The goals of the Bankhead-Coley Program are to significantly expand cancer research capacity and cancer treatment 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, proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;

⁵Section 215.5601(1)(d), F.S.

⁶Chapter 99-167, L.O.F.

⁷Section 215.5602(2), F.S.

⁸Chapter 2001-73, L.O.F.

⁹Chapter 2003-414, L.O.F.

¹⁰The efforts to improve cancer research are outlined in s. 381.921, F.S.

- Encouraging the employment of bioinformatics 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;
- Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research;
- Aiding in other multidisciplinary, research-support activities for the advancement of cancer research;
- Improving both research and treatment through greater participation in clinical trials networks; and
- Reducing the impact of cancer on disparate groups.

Biomedical Research Program Funding

The Florida Biomedical Research Program distributes grant awards for one-, two-, or three-year increments. Unspent awards are deposited back into the Biomedical Research Trust Fund after five years. Any university or research institute in Florida may apply for grant funding to support the goals of either the King Program or Bankhead-Coley Program. All qualified investigators in the state, regardless of the institution, have an equal opportunity to compete for funding. Applications are accepted annually and awards are announced every June/July. After the awards are announced, the program obtains a signed contract, final budget, and the required study approvals from the grant recipient. Funds are only released to recipients on an as-needed basis and the undispersed, but obligated funds, are held in an interest bearing account. The accrued interest is held in the Biomedical Research Trust Fund of DOH.

The extent of funding for these programs has varied significantly from year-to-year. In FY 2012-13, funding for biomedical research occurred through several appropriations:

The King Program received \$7.2 million from funds in the Biomedical Research Trust Fund. This funding was allocated through grants.¹¹

- The total awarded under the King Program has been approximately \$3.9M for this fiscal year.
- The largest research award under the King Program was \$400,000.

The Bankhead-Coley Program received \$5 million from funds in the Biomedical Research Trust Fund. These funds were allocated through grants.¹²

- The total awarded under the Bankhead/Coley Program has been approximately \$3.6M for this fiscal year.
- The largest research award under the Bankhead/Coley Program was \$374,000.

Direct appropriations to institutions:¹³

- H. Lee Moffitt Cancer Center and Research Institute (Moffitt Cancer Center) received \$5 million from funds in the Biomedical Research Trust Fund and \$10,576,930 in the General Appropriations Act, Section 2 – Education: Division of Universities.
- Shands Cancer Hospital received \$5 million from funds in the Biomedical Research Trust Fund and \$2.5 million from nonrecurring General Revenue.
- Sylvester Comprehensive Cancer Center at the University of Miami received \$5 million from funds in the Biomedical Research Trust Fund and \$2.5 million from nonrecurring General Revenue.
- Sanford-Burnham Medical Research Institute received \$3 million from General Revenue.

¹¹ Email correspondence with DOH staff, on file with the Health Quality Subcommittee staff.

¹² *Id.*

¹³ *Id.*

Other Cancer Related Bodies in Florida

Cancer Control and Research Advisory Council (CCRAB)

In 1979, the Florida Cancer Control and Research Act was created pursuant to, s. 1004.435, F.S., along with CCRAB. CCRAB is housed within the H. Lee Moffitt Cancer Center and Research Institute, Inc. CCRAB consists of 35 members, including appointees by: the Governor, Speaker of the House of Representatives, President of the Senate and other persons representing the following:¹⁴

American Cancer Society, Florida Tumor Registrars Association, Sylvester Comprehensive Cancer Center of the University of Miami, DOH, University of Florida Shands Cancer Center, Agency for Health Care Administration, Florida Nurses Association, Florida Osteopathic Medical Association, American College of Surgeons, School of Medicine of the University of Miami, College of Medicine of the University of Florida, NOVA Southeastern College of Osteopathic Medicine, College of Medicine of the University of South Florida, College of Public Health of the University of South Florida, Florida Society of Clinical Oncology, Florida Obstetric and Gynecologic Society, Florida Ovarian Cancer Alliance Speaks, Florida Medical Association, Florida Pediatric Society, Florida Radiological Society, Florida Society of Pathologists, Moffitt, Florida Dental Association, Florida Hospital Association, Association of Community Cancer Centers, statutory teaching hospitals, Florida Association of Pediatric Tumor Programs, Inc., Cancer Information Services, Florida Agricultural and Mechanical University Institute of Public Health, Florida Society of Oncology Social Workers, and consumer advocates from the general public.

CCRAB formulates and makes recommendations to the State Surgeon General, the Board of Governors, and the Florida Legislature. These recommendations include, but are not limited to, approval of the state cancer plan, cancer control initiatives, and the awarding of grants and contracts, as funds are available, to establish, or conduct programs in cancer control or prevention, cancer education and training, and cancer research. Technical Advisory Groups are formed by the Council to review such areas as the state cancer plan evaluation, tobacco use prevention, cancer disparities, cancer-related data, and legislative initiatives.

Regional Cancer Control Collaborative

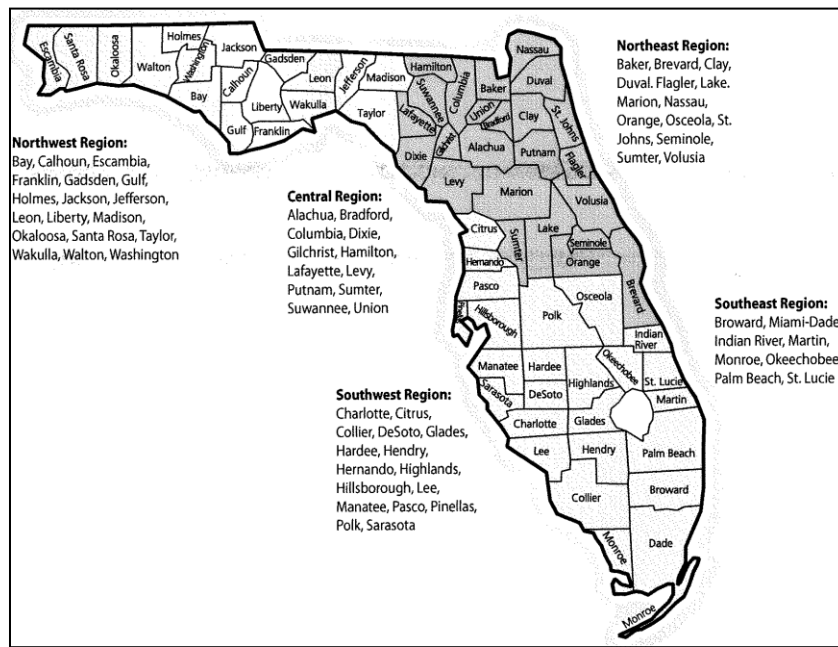
According to the Florida Cancer Plan, due to Florida's geography and diversity, there was a need for more localized planning to create a true comprehensive cancer control plan.¹⁵ Thus, in 2000, the U.S. Congress appropriated funds to develop comprehensive regional cancer control plans in Florida. Funding was awarded to the University of Miami, Sylvester Comprehensive Cancer Center through a cooperative agreement with the CDC as part of their Cancer Control Collaborative (CCC) Program. This resulted in the Florida Comprehensive Cancer Control Initiative, which established four regional cancer control collaboratives covering all 67 Florida counties (see map below).¹⁶ From 2000 to 2003, cancer control stakeholders in each of the four regions were invited to participate in a strategic planning process. From this, four regional cancer control plans were developed. In addition to regional goals, objectives, and strategies, each plan included detailed county-level cancer and demographic data, as well as a directory of cancer resources. The regional plans are an integrated Florida Cancer Plan.¹⁷

¹⁴ Section 1004.435(4)(a), F.S.

¹⁵ Florida Department of Health, Florida State Cancer Plan 2010, available at: <http://www.doh.state.fl.us/Family/cancer/ccc/plan/index.html> (last viewed March 27, 2011).

¹⁶ *Id.*

¹⁷ *Id.*



Statewide Cancer Registry

Section 385.202, F.S., requires each hospital or other licensed facility to report to 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 to include Prostate Cancer.¹⁸ DOH, or a medical organization pursuant to a contract with DOH, is required to maintain and make available for research such information in a statewide cancer registry.

Commission on Cancer for the American College of Surgeons

The Commission on Cancer (CoC) Accreditation Program encourages hospitals, treatment centers, and other facilities to improve their quality of patient care through various cancer-related programs. These programs focus on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care.¹⁹

Accredited cancer programs are assigned an accreditation category that describes the services available at the facility and the number of cases. Category assignments are made by CoC staff and are retained, unless there are changes to the services provided or the facility caseload over a three-year period. The cancer accreditation categories include the:²⁰

- Academic Comprehensive Cancer Program;
- Community Cancer Program;
- Comprehensive Community Cancer Program;
- Free Standing Cancer Center Program;
- Hospital Associate Cancer Program;
- Integrated Network Cancer Program;
- NCI-Designated Comprehensive Cancer Center Program;
- Pediatric Cancer Program; and
- Veterans Affairs Cancer Program.

¹⁸ Chapter 78-171, L.O.F.

¹⁹ American Colleges of Surgeons, Cancer Programs: Accreditation, available at: <http://www.facs.org/cancer/coc/approval.html> (last visited on March 12, 2013).

²⁰ American College of Surgeons Cancer Programs Categories of Accreditation for a description of the distinguishing characteristics of these categories, available at: <http://www.facs.org/cancer/coc/categories3.html> (last visited on March 12, 2013).

Effects of Proposed Changes

Cancer Center of Excellence Award

The bill creates s. 381.925, F.S., the Cancer Center of Excellence Award to recognize hospitals, treatment centers, and other providers in Florida that demonstrate excellence in patient-centered, coordinated care for persons undergoing cancer treatment and therapy.

The bill directs CCRAB and BRAC to form a joint committee to develop rigorous performance measures, a rating system, and a rating standard for earning an Award by January 1, 2014.

The bill requires DOH to develop an application form and annually conduct two application cycles for the Award.

The State Surgeon General is required to appoint a team of independent evaluators to assess and conduct onsite evaluations of applicants for the Award, and to notify the Governor of the applicants eligible to receive the Award. The bill also requires the State Surgeon General to report to the President of the Senate and the Speaker of the House of Representatives the status of implementing the Award program by January 31, 2014 and by December 15 annually thereafter.

The bill provides that an Award will be recognized for three years, authorizes awardees to use the Award designation in advertising and marketing, and provides that awardees will be given preference in certain competitive solicitations.

Reporting Requirements for Recipients of Direct Appropriations

The bill creates new reporting requirements for recipients of appropriations for biomedical and/or cancer research or related activities that do not have an existing statutory reporting requirements. The bill amends s. 215.5602(12), F.S., to require annual fiscal-year progress reports describing the use of the funds to the President of the Senate and the Speaker of the House of Representatives by December 15.

Endowed Research Chair Program

The bill amends s. 381.922, F.S., to create an endowment program for cancer research chairs. The bill requires DOH to award endowments to integrated cancer research and care institutions for establishing a research chair and provides that the purpose of the endowment is to secure funding for at least seven years to attract and experienced and promising researcher who specializes in cancer-related research.

The bill requires institutions that receive endowed chair funding to submit an annual progress report to the President of the Senate and the Speaker of the House of Representatives by December 15th.

The research chair endowments are contingent upon a specific appropriation in the GAA.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

Endowments for the research chairs are contingent upon a specific appropriation in the General Appropriation Act for this purpose. The Fiscal Year 2013-14 GAA included a \$10 million appropriation for research chair endowments. Proviso language allocates the funding to the following institutions:

\$3,333,333 - H. Lee Moffitt Cancer Center and Research Institute
\$3,333,333 - Shands Cancer Hospital at the University of Florida
\$3,333,334 - Sylvester Cancer Center at the University of Miami

DOH may incur additional administrative costs to support the programs established in the bill, but these costs are not expected to be significant.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Although application for the Award is voluntary, providers in the state who wish to be designated as such will incur indeterminable costs to align their programs with the standards contemplated by this bill. Providers receiving the award may be able to secure additional patient revenues as a result of the distinction of their care.

Additionally, providers that receive appropriations for biomedical and/or cancer research or related activities are required to submit annual fiscal-year progress reports that describe the use of funds to the President of the Senate and the Speaker of the House of Representatives. These recipients may incur costs related to the annual progress reporting but these costs are not expected to be significant.

D. FISCAL COMMENTS:

None.