

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** PCB HQS 13-01 Quality Cancer Care and Research

**SPONSOR(S):** Health Quality Subcommittee; Oliva

**TIED BILLS:** **IDEN./SIM. BILLS:**

| REFERENCE                                | ACTION    | ANALYST | STAFF DIRECTOR or<br>BUDGET/POLICY CHIEF |
|--|-----------|---------|--|
| Orig. Comm.: Health Quality Subcommittee | 12 Y, 0 N | Holt    | O'Callaghan                              |

### SUMMARY ANALYSIS

The bill creates 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. This bill provides for the development of performance measures, a rating system, and a rating standard that must be achieved to be eligible for the three-year recognition. A team of independent evaluators is established by the bill to determine if such performance measures and standards are achieved or exceeded. The award and designation may be used in the provider's advertising and marketing for up to three years and it entitles the recipient to preferential consideration in competitive solicitations by a state agency or state university.

The bill also provides for endowments to cancer research institutions in the state to establish a funded research chair that will attract and retain a promising researcher in order to serve as a catalyst to attract other national grant-producing researchers to the state. The endowments are contingent upon funding in the General Appropriations Act.

This bill, if funds are appropriated, would have a fiscal impact on the state and no fiscal impact on local governments.

The bill has an effective date of July 1, 2013.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

Cancer is the leading cause of death in Florida. Florida has the second-highest number of new cases of cancer 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.<sup>1</sup> 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.<sup>2</sup>

#### The Biomedical Research Program

The Florida Biomedical Research Program within the Department of Health (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.<sup>3</sup> A component of the Biomedical Research Program was the Biomedical Research Advisory Council (BRAC).<sup>4</sup> The 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.

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

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<sup>1</sup> H. Lee Moffitt Cancer Center is the only designated cancer center.

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

<sup>3</sup> Chapter 99-167, L.O.F.

<sup>4</sup> Section 215.5602(3), F.S.

At inception, the program was intended to be supported by funds from the Lawton Chiles Endowment Fund,<sup>5</sup> but a specific appropriation amount was not statutorily indicated.<sup>6</sup> Statute<sup>7</sup> 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. Today, appropriations made from the interest earnings in the Lawton Chiles Endowment Fund are placed in a special appropriation category called the James and Esther King Biomedical Research Program and deposited into the Biomedical Research Trust Fund in the DOH to support the program.

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.<sup>8</sup> In 2003, the Florida Biomedical Research Program was renamed the “James and Esther King Biomedical Research Program (King program).”<sup>9</sup>

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 the 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.<sup>10</sup>

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, those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
- 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;

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<sup>5</sup>Section 215.5601(1)(d), F.S.

<sup>6</sup>Chapter 99-167, L.O.F.

<sup>7</sup>Section 215.5602(2), F.S.

<sup>8</sup>Chapter 2001-73, L.O.F.

<sup>9</sup>Chapter 2003-414, L.O.F.

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

- 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 as they inure to 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 periods. 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 undisbursed, 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 2012-2013, funding for biomedical research occurred through several appropriations:

The King Program received \$5 million from DOH which was funded from the tobacco surcharge. This funding was allocated through grants.<sup>11</sup>

- The total awarded under the King Program was approximately \$3.9M.
- The largest research award under the King Program was \$400,000.

The Bankhead-Coley Program received \$5 million from DOH which was funded from the tobacco surcharge. These funds were allocated through grants.<sup>12</sup>

- The total awarded under the Bankhead/Coley Program was approximately \$3.6M.
- The largest research award under the Bankhead/Coley Program was \$374,000.

Direct appropriations to institutions:<sup>13</sup>

- Moffitt received \$5 million from DOH which was funded from the tobacco surcharge and \$10,576,930 in the General Appropriations Act (Section 2 – Education: Division of Universities).
- Shands Cancer Hospital received \$5 million from DOH which was funded from tobacco surcharge and \$2.5 million from General Revenue.
- Sylvester Comprehensive Cancer Center at the University of Miami received \$5 million from which was funded from the tobacco surcharge and \$2.5 million from General Revenue.
- Sanford-Burnham Medical Research Institute received \$3 million from General Revenue.

### 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 the Cancer Control Research Advisory Council (CCRAB). The CCRAB is housed within the H. Lee Moffitt Cancer Center and Research Institute, Inc. The CCRAB consists of 35 members,

<sup>11</sup> Email correspondence with DOH staff, on file with the Health Quality Subcommittee staff.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

including appointees by: the Governor and Speaker of the House of Representatives, the President of the Senate and other persons representing the:<sup>14</sup>

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.

The 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.<sup>15</sup> 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).<sup>16</sup> 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.<sup>17</sup>

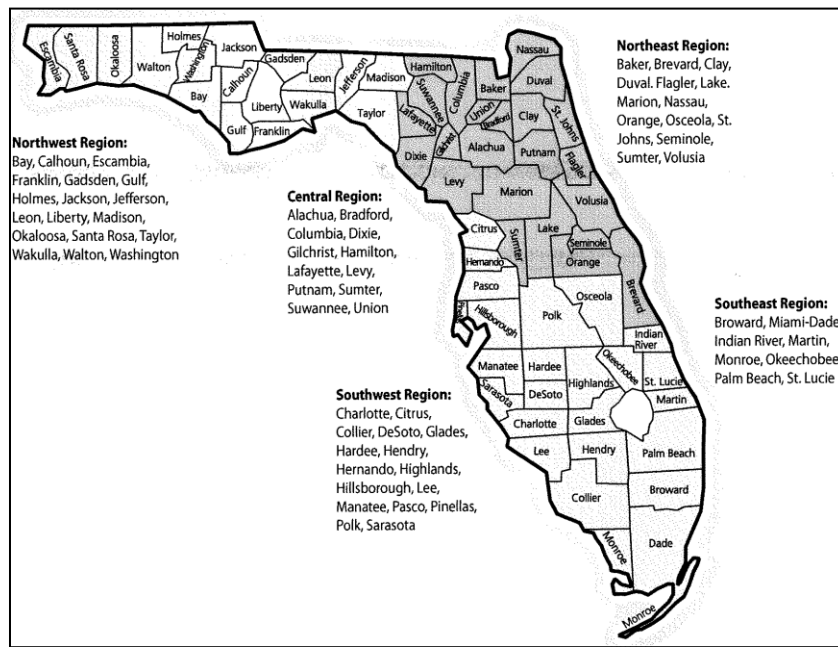
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<sup>14</sup> Section 1004.435(4)(a), F.S.

<sup>15</sup> 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).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*



## 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 to include Prostate Cancer.<sup>18</sup> 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.

## 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.<sup>19</sup>

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:<sup>20</sup>

- 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.

<sup>18</sup> Chapter 78-171, L.O.F.

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

<sup>20</sup> 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. The three-year award recognizes hospitals, treatment centers, or other providers in Florida that demonstrate excellence in patient-centered, coordinated care for persons undergoing cancer treatment and therapy.

Winning the award affords the recipient preference in competitive solicitations for state funds. Moreover, the award may be used in advertising and marketing campaigns.

DOH must conduct biannual application cycles and to qualify for the award the applicant must at least:

- Maintain a license in this state which authorizes health care services be provided.
- Not have been disciplined or subject to any administrative enforcement action by the state or federal regulatory authority within the preceding 3 years.
- Be accredited by the Commission on Cancer of the American College of Surgeons.
- Actively participate in at least one regional cancer control collaborative that is operating pursuant to DOH's cooperative agreement with the CDC's National Comprehensive Cancer Control Program.
- Meet enhanced cancer care coordination standards set by the CCRAB and BRAC that focus on:
  - Coordination of care by cancer specialists, nursing and allied health professionals.
  - Psychosocial assessment and services.
  - Suitable and timely referrals and follow-up.
  - Providing accurate and complete information on treatment options, including clinical trials, which consider each person's needs, preferences, and resources, whether provided by the center or other providers.
  - Participation in a comprehensive network of cancer specialists of multiple disciplines allowing the patient to consult with variety of experts to evaluate other treatment options.
  - Family services and support.
  - Aftercare and survivor services.
  - Patient and family satisfaction survey results.

The State Surgeon General is required to appoint a 5-member team of independent evaluators to assess applicants to determine eligibility. Also, an application is to be evaluated independently of any other application. The team is comprised of the following in any combination:

- No more than 5 health care practitioners or health care facilities not licensed in Florida that provide cancer treatment or diagnosis;
- No more than 3 members from the Florida Cancer Control and Research Advisory Council;
- No more than 2 members from the Biomedical Research and Advisory Council; and
- No more than 1 layperson member who has experience as a cancer patient or family member who did not receive care from the facility being evaluated.

Evaluators are to be independent and free of any conflict of interest with respect to a health care provider or facility licensed in the state. Evaluators are required to sign a conflict of interest attestation before appointment. Two evaluators are permitted, as needed, to verify onsite documentation submitted with an application.

Each evaluator must report to the State Surgeon General the applicants that achieved or exceeded the required score based on a rating system developed jointly by the CCRAB and BRAC. The CCRAB and BRAC are also required to develop an application form, rigorous performance measures, and a rating standard that must be achieved to document and distinguish a cancer center that excels in providing

quality, comprehensive, and patient-centered coordinated care program. The CCRAB and BRAC are directed to advise the State Surgeon General with respect to the Cancer Center for Excellence Award.

The bill requires the State Surgeon General to notify the Governor of the providers that are eligible for an award and submit an annual report to the Legislature beginning January 31, 2014. The report must include the status implementation; metrics on the number of applicants, number of award recipients by application cycle, list of awardees, and recommendations for legislation to strengthen the program.

The bill clarifies that the application submitted for a Cancer Center for Excellence Award is not an application for licensure, and therefore the provisions of s. 120.60, F.S., related to licensure do not apply. Additionally, the bill states that the notification by the State Surgeon General to the Governor of an eligible award entity is not considered final agency action, thus the provisions in ch.120, F.S., relating to challenges to agency action do not apply.

The bill grants DOH authority to adopt rules related to the application cycles and the submission of the application form.

#### Bankhead-Coley endowments for research chair

The bill creates s. 381.922(4), F.S., under the Bankhead-Coley program, to authorize the establishment of endowments for cancer research institutions within the state to fund an endowed research chair.

The endowment requires a specific appropriation, which will be used to establish endowment awards enabling a cancer research institution to provide stable funding for at least 7 years to recruit and retain experienced promising researchers. The endowed chairs are intended to specialize in a cancer-related field of research that will facilitate coordination among research institutions within the state and attract other promising researchers and national funding.

The research institution that receives an endowed chair must submit a report to the Governor, the President of the Senate and Speaker of the House of Representatives describing the research program and the responsibilities of the endowed chair. Upon final selection of the researcher, or if a replacement is needed for the original endowed chair, the research institution must notify the chairs of the appropriations committees of the Senate and House of Representatives of the name of the researcher and specific information about the endowment budget and research responsibilities. The research institution is required to report annually to the President of the Senate and the Speaker of the House of Representatives the following information pertaining to the endowment:

- Chair's name.
- Current salary.
- Research responsibilities.
- Percentage of time devoted to research if the chair also serves as a member of faculty.
- Reports on research progress and progress toward achieving the goals of the Bankhead-Coley program.
- Endowment expenditures and balance.
- Interest rate and interest earned on the endowment.

#### B. SECTION DIRECTORY:

**Section 1.** Creates s. 381.925, F.S., related to the Cancer Center of Excellence Award.

**Section 2.** Amends s. 215.5602, F.S., related to the James and Esther King Biomedical Research program.

**Section 3.** Amends s. 381.922, F.S., related to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

**Section 4.** Amends s. 1004.435, F.S., relating to the Florida Cancer Control and Research Advisory Council; creation; and composition.

**Section 5.** Provides an effective date of July 1, 2013.



## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

See FISCAL COMMENTS.

#### 2. Expenditures:

See FISCAL COMMENTS.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

#### 1. Revenues:

None.

#### 2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Although application for the Cancer Center of Excellence 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.

### D. FISCAL COMMENTS:

The bill requires DOH to incur administrative costs to support the two programs established in the bill, but these costs are not expected to be significant. The amount of the endowments for the research chairs would need to be appropriated in the General Appropriations Act and would be significant.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

#### 1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

#### 2. Other:

None.

### B. RULE-MAKING AUTHORITY:

The bill authorizes DOH sufficient authority to implement the provisions of the bill.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

Although the bill requires the Surgeon General to notify the Governor regarding the providers that are "eligible" to receive the Cancer Center of Excellence Award, it is not clear who actually grants the award and whether all those eligible to receive the award are automatically granted an award.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES