## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7153 (PCB HQS 13-01) Quality Cancer Care and Research

SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Oliva

TIED BILLS: IDEN./SIM. BILLS: CS/CS/SB 1660

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	12 Y, 0 N	Holt	O'Callaghan
1) Health Care Appropriations Subcommittee	11 Y, 1 N	Rodriguez	Pridgeon
2) Health & Human Services Committee	13 Y, 0 N, As CS	Holt	Calamas

# **SUMMARY ANALYSIS**

The bill creates the Cancer Center of 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 establishes a joint committee, comprised of a certain number of members of the Biomedical Research Advisory Council (BRAC) and the Cancer Control Research Advisory Council (CCRAB), to develop performance measures, a rating system, and a rating standard that a provider must achieve to be eligible for the Award. Both, the BRAC and CCRAB, have final approval authority over the performance measures, rating system, and rating standard developed by the joint committee. The joint committee is also required to develop an application form to be used by applicants for the Award.

A team of independent evaluators is required to evaluate the Award applicants to determine whether the performance measures and standards have been met and to advise the State Surgeon General which applicants are eligible for the Award. Under the bill, the State Surgeon General's responsibilities include reviewing the evaluation process, granting Awards, notifying the Governor which providers have been granted an Award, and submitting an annual report pertaining to the Award program to the Legislature. The Award is valid for three years and may be used for advertising and marketing purposes during that time. In addition, the recipient of the Award is entitled to preferential consideration in competitive solicitations related to cancer care or research undertaken by a state agency or state university.

The bill also provides for 7-year endowments to cancer research and care institutions in the state to fund research chairs in order to attract and retain promising and national grant-producing researchers to Florida and facilitate coordination among research institutions within the state. The bill provides for the responsibilities of the research chair and specifies that the endowments for the chair are contingent upon funding in the General Appropriations Act.

The bill enhances certain existing reporting requirements, and creates new reporting requirements, related to certain types of state-funded research, such as research related to cancer and tobacco-related diseases.

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

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h7153c.HHSC

#### **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 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. 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.<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> 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;
- A representative of the American Cancer Society;
- A representative of the American Heart Association; and

<sup>4</sup> Section 215.5602(3), F.S. **STORAGE NAME**: h7153c.HHSC

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

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

A representative of the American Lung Association.

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.

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;
- 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 other multidisciplinary, research-support activities;

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

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

Section 215.5602(2), F.S.

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

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

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

- Improving 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, the King Program received \$7.2M from funds in the Biomedical Research Trust Fund. This funding was allocated through grants.<sup>11</sup> 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.

In FY 2012-13, the Bankhead-Coley Program received \$5M from funds in the Biomedical Research Trust Fund. These funds were allocated through grants. 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 (non-grant-related) appropriations were made to several institutions:<sup>13</sup>

- H. Lee Moffitt Cancer Center and Research Institute (Moffitt Cancer Center) received \$5M from funds in the Biomedical Research Trust Fund and \$10.5M in the General Appropriations Act (Section 2 – Education: Division of Universities).
- Shands Cancer Hospital received \$5M from funds in the Biomedical Research Trust Fund and \$2.5M from nonrecurring General Revenue.
- Sylvester Comprehensive Cancer Center at the University of Miami received \$5M from funds in the Biomedical Research Trust Fund and \$2.5M from nonrecurring General Revenue.
- Sanford-Burnham Medical Research Institute received \$3M from General Revenue.

## Other Cancer-Related Entities 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). 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

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

<sup>&</sup>lt;sup>12</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> Section 1004.435(4)(a), F.S. **STORAGE NAME**: h7153c.HHSC

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 CCRAB 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). 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

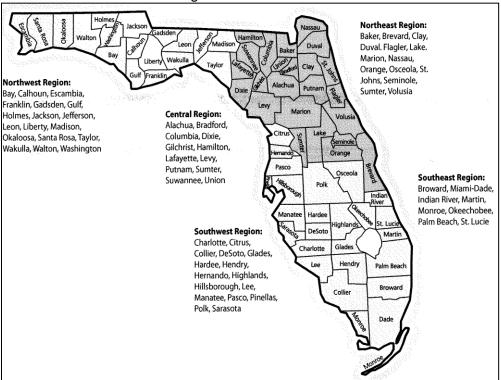
<sup>17</sup> *Id*.

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<sup>&</sup>lt;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>&</sup>lt;sup>16</sup> *Id*.

# Florida Regional Cancer Control Collaboratives



# 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.<sup>18</sup> 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. <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;

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

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

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

- Pediatric Cancer Program; and
- Veterans Affairs Cancer Program.

# **Effect of Proposed Changes**

# Cancer Center of Excellence Award

The bill creates s. 381.925, F.S., the Cancer Center of Excellence Award (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 by a state agency or university, which relate to cancer care or research. Moreover, the Award may be used in advertising and marketing campaigns.

After January 1, 2014, DOH must conduct biannual application cycles. To qualify for the award, the applicant, at a minimum, must:

- Maintain a license in this state which authorizes health care services to be provided.
- Not have been disciplined or subject to any administrative enforcement action by the state or federal regulatory authority within the preceding three 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 the Florida Comprehensive Cancer Control Program's cooperative agreement with
  the CDC's National Comprehensive Cancer Control Program.
- Demonstrate excellence in and dissemination of scientifically rigorous cancer research.
- Integrate training and education of biomedical researchers and health care professionals.
- Meet enhanced cancer care coordination standards set by CCRAB and BRAC that focus on:
  - Coordination of care by cancer specialists and 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.

In addition to the standards listed above, an applicant must be evaluated against performance measures, a rating system, and a rating standard developed by a joint committee comprised of 7 members of the CCRAB and 6 members of the BRAC. The joint committee is required to develop the performance measures, rating system, and standard by January 1, 2014, and review such criteria triennially thereafter. The CCRAB and BRAC must approve the criteria developed by the joint committee before an applicant is evaluated for eligibility as a recipient of the Award. Members of the joint committee may not be compensated for their services, but may be reimbursed for travel or other necessary expenses. DOH is required to provide staff and other support to the joint committee.

The State Surgeon General is required to appoint a five member team of independent evaluators to assess applicants, using the criteria developed by the joint committee, 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:

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- No more than five health care practitioners or health care facilities not licensed in Florida that provide cancer treatment or diagnosis;
- No more than three members from the Florida Cancer Control and Research Advisory Council;
- No more than two members from the Biomedical Research and Advisory Council; and
- No more than one 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 necessary, to conduct an onsite evaluation to verify submitted application documentation.

Each evaluator must report to the State Surgeon General the applicants that achieved or exceeded the criteria developed by the joint committee. The CCRAB and BRAC are required to advise the State Surgeon General with respect to the Award program. The State Surgeon General must determine if the review process was objective and consistent and if so, grant the Award.

The bill requires the State Surgeon General to notify the Governor which providers have received the Award and to submit a report to the Legislature beginning January 31, 2014, as to the status of the implementation of the Award program. Thereafter, every December 15, a report must be submitted, which includes the number of applicants and award recipients by application cycle, a list of recipients, and recommendations to strengthen the program.

The bill clarifies that the application submitted for an 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 grant of the Award by the State Surgeon General 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.

## **Endowments for Research Chairs**

The bill creates s. 381.922(4), F.S., under the Bankhead-Coley Program, to authorize each integrated cancer research and care institution within the state to apply for an endowment to fund a research chair for at least seven years. The endowments serve to attract experienced and promising researchers to fill each research chair position, because the continued employment of each chair is not contingent upon grant awards associated with time-limited projects. The endowed chairs are intended to specialize in a cancer-related field of research that will facilitate coordination among research institutions within the state; attract other promising researchers and national funding; and assist in the sharing of knowledge, resources, and facilities to spur commercialization of scientific or technological advancements related to cancer research.

The endowment requires a specific appropriation. The bill clarifies that the endowment must not be derived from funds appropriated pursuant to s. 215.5602(12), F.S., for research related to cancer or tobacco-related diseases. The recipient of the endowment is required to place the funds in an interest bearing account and the interest must be added to the principal balance of the endowment. If an institution must replace an endowed research chair, the endowment must cease funding expenses associated with the endowed research chair, other than for reasonable costs for recruitment, until a replacement chair has been retained. While the chair is vacant, the endowment must continue to earn interest and all earnings must be added to the balance of the endowment. The chair vacancy tolls the 7-year timeframe for the endowed research chair.

Once the research institution has selected a research chair, it must notify the chairs of the appropriations committees of the Senate and the House of Representatives. Additionally, the research institution must submit an annual report by December 15 to the Governor, the President of the Senate and Speaker of the House of Representatives that, at a minimum, must:

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- Describe the research program or institution;
- Identify the research chair;
- Indicate the amount of endowment funds used for the chair's salary;
- State the endowment balance, expenditures, interest rate, and interest earned;
- Describe the general responsibilities of the research chair;
- Identify the percentage of time devoted to research and research-related activities if the chair also serves as a member of faculty;
- Describe the status of recruitment activities and identify any barriers to attracting promising researchers to the state;
- Identify any federal or private grants or donations generated as a result of the chair's efforts;
   and
- Describe initiatives that spur the sharing of knowledge, facilities, and resources and facilitate commercialization of scientific or technological advancements related to cancer research.

# Reporting Requirements of Recipients of State Funding

The bill requires DOH to submit an annual report by December 15 to the Governor and the Legislature providing a list of cancer research projects supported by the Bankhead-Coley Program. For each listed project the report must also:

- Specify the total grant amount;
- Include any amount of unobligated or unspent funds;
- Itemize all expenditures;
- State whether the research is ongoing or completed;
- Provide an estimated date of completion; and
- Name the recipients of research grants, denote the amount awarded, provide the intended use
  of the award, and include a brief description of the reason why the recipient was chosen.

The bill also enhances CCRAB's existing annual reporting requirement by requiring the report to specify for each listed research project the total amount granted under the King Program, any unobligated or unspent funds, itemization of all expenditures, and the estimated completion date.

The bill creates reporting requirements beginning July 1, 2014, for recipients of specific appropriations under s. 215.5602(12), F.S., for research related to cancer or tobacco-related diseases. An annual fiscal-year progress report must be submitted by December 15. The report must:

- Contain an itemization of all expenditures:
- Provide the amount of unobligated or unspent funds;
- Include a report from an independent audit of receipts and payments of state funds, which may be funded by a portion of the appropriation;
- Specify the research, if any, funded by the appropriation, as well as the expected and actual results of the research;
- Describe any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline and status for the project, if applicable;
- Include a job description, annual salary and benefits, and performance reviews for all funded staff positions, if applicable;
- Identify any federal or private grants or donations generated as a result of the appropriation or activities funded by the appropriation; and
- Include an assessment of the direct and indirect economic impact of the appropriation, including
  a description of the contribution of the research to scientific or technological advancement and
  the economic impact of any federal and private grants or donations generated as a result of the
  appropriation or activities funded by the appropriation.

#### B. SECTION DIRECTORY:

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- **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 cancer control and research.
- **Section 5.** Provides an effective date of July 1, 2013.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

## A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

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 amount of the endowments for the research chairs are subject to an unknown appropriation amount, to be specified in the General Appropriations Act, and would be significant. DOH may incur additional administrative costs to support the two programs established in the bill, but these costs are not expected to 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:

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None.

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 16, 2013, the Health and Human Services Committee adopted a strike-all amendment to HB 7153 and two amendments to the strike-all amendment. The bill was reported favorably as a committee substitute. The strike-all amendment, as amended:

- Creates a 13-member joint committee of 7 members of the Cancer Control and Research Advisory Council (CCRAB) and 6 members of the Biomedical Research Advisory Council (BRAC) to develop the evaluation standards for the Cancer Center of Excellence Award.
- Deletes the requirement that the full BRAC and CCRAB create the standards.
- Provides that the committee members serve without compensation, but may be reimbursed for certain expenses.
- Requires DOH to provide staff and other assistance to the committee.
- Sets a start date for applications for Cancer Center of Excellence Awards.
- Clarifies that the State Surgeon General grants the Cancer Center of Excellence Award.
- Clarifies that an integrated cancer research and care institution must apply to DOH, using a form developed by DOH, to receive funds for an endowed research chair.
- Specifies that the funds appropriated for an endowed research chair must be independent of funds appropriated pursuant to s. 215.5602(12), F.S.
- Allows DOH to award multiple research chair endowments; but only one per institution.
- Specifies the duties of the endowed research chair.
- Creates, and enhances existing, reporting requirements for institutions receiving funding related to cancer care and research.

This analysis is drafted to the committee substitute.

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