

This bill substantially amends sections 215.5602, 381.922, and 1004.435, Florida Statutes.

The bill creates section 381.925, Florida Statutes.

II. Present Situation:

Cancer is the general name for a group of more than 100 diseases. Although there are many kinds of cancer, all cancers start because abnormal cells grow out of control. Untreated cancers can cause serious illness and death. Half of all men and one-third of all women in the U.S. will develop cancer during their lifetimes.¹

About 1,660,290 new cancer cases are expected to be diagnosed in 2013 in the United States, with approximately 118,290 of those occurring in Florida. In 2013, about 580,350 Americans are expected to die of cancer, almost 1,600 people per day. Cancer is the second most common cause of death in the United States, exceeded only by heart disease, accounting for nearly one of every four deaths. The National Cancer Institute estimates that approximately 13.7 million Americans with a history of cancer were alive on January 1, 2012. Some of these individuals were cancer free, while others still had evidence of cancer and may have been undergoing treatment.²

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.³ 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. Florida has fewer designated cancer centers than peer states. For example, New York has four centers, Texas has three, and California has ten.⁴

Florida Cancer Control and Research Advisory Council

The Florida Cancer Control and Research Advisory Council (Council) is created within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt).⁵ The Council:

- Advises the Board of Governors, the state surgeon general, and the Legislature on cancer control and research in Florida;
- Annually approves the Florida Cancer Plan;
- Provides recommendations for the Florida Cancer Plan to include the coordination and integration of plans concerned with cancer control and research provided by other stakeholders;
- Formulates and recommends to the state surgeon general:

¹ American Cancer Society, *What is Cancer*, available at: <http://www.cancer.org/cancer/cancerbasics/what-is-cancer> (last visited March 12, 2013).

² American Cancer Society, *Cancer Facts and Figures 2013*, available at: <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-036845.pdf> (last visited March 12, 2013).

³ H. Lee Moffitt Cancer Center is the only designated cancer center.

⁴ Department of Health, *SB 1660 Bill Analysis* (March 8, 2013), (on file with the Senate Health Policy Committee).

⁵ s. 1004.435(4), F.S.

- A plan for the care and treatment of persons suffering from cancer,
- Standard requirements for organization, equipment, and conduct of cancer units or departments in hospitals and clinics, and
- The designation of cancer units following a survey of needs and facilities for treatment of cancer throughout the state;
- Recommends grant awards and contracts to qualified recipients;
- Develops educational materials and programs; and
- Recommends rules and methods of implementing or enforcing laws concerned with cancer control, research, and education.

The Council consists of 35 members including appointees by the speaker of the House of Representatives, the president of the Senate, and the governor and other persons representing the: American Cancer Society, Florida Tumor Registrars Association, Sylvester Comprehensive Cancer Center of the University of Miami, Department of Health (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.

Biomedical Research Advisory Council (BRAC)

The Biomedical Research Advisory Council (BRAC) is established within the DOH.⁶ The BRAC advises the state surgeon general as to the direction and scope of the state's biomedical research program. This responsibility includes:

- 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.

⁶ s. 215.5602(3), F.S.

The BRAC consists of 11 members, including 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; the president of the Senate with expertise in behavioral or social research, and from a cancer program approved by the American College of Surgeons; and the governor with expertise in biomedical research, from a research university in Florida, and one representing the general public; and other persons representing the American Cancer Society, American Heart Association, and American Lung Association.

Commission on Cancer for the American College of Surgeons

The Commission on Cancer (CoC) Accreditation Program⁷ 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.

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:⁸

- 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
- Veterans Affairs Cancer Program.

Cancer Control Collaborative

In 2001, the Florida Comprehensive Cancer Control Program (CCC Program) within the DOH was created through a cooperative agreement with the federal Centers for Disease Control and Prevention (CDC). The main objective of the cooperative agreement is to reduce the cancer burden through a collaborative effort with public and private partners. The CCC Program supports regional cancer collaboratives, which are networks of volunteer groups to enhance communications and efforts to reduce cancer incidence, morbidity, and mortality through prevention, early detection, treatment, rehabilitation, and palliation. There are five regional

⁷ See <http://www.facs.org/cancer/coc/approval.html> (last visited on March 12, 2013).

⁸ See 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).

cancer control collaboratives in Florida: the Northwest Region, Northeast Region, North Central Region, Southwest Region, and the Southeast Region.⁹

State Supported Cancer Research in Florida

The Florida Biomedical Research Programs administered by the DOH includes two grant-funding programs: the James and Esther King Biomedical Research Program (King Program)¹⁰ and the Bankhead-Coley Cancer Research Program (Bankhead-Coley Program).¹¹ Annually the Florida Legislature appropriates funds for competitive awards for biomedical research related to the goals of these two programs. 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.

The goals of the Bankhead-Coley Program are 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 resource 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;
 - 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.
- Improve both research and treatment through greater participation in clinical trials networks.
- Reduce the impact of cancer on disparate groups.

⁹ <http://www.doh.state.fl.us/family/cancer/ccc/index.html> (last visited March 12, 2013).

¹⁰ s. 215.5602, F.S.

¹¹ s. 381.922, F.S.

Any university or research institute in Florida may apply for grant funding to support the goals of either program and all qualified investigators in the state, regardless of institution, have equal opportunity to compete for funding. All awards are made based on scientific merit, as determined by open competitive peer review.

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 the DOH which was funded from the tobacco surcharge. This funding was allocated through grants.
 - The total awarded under the King Program was \$3,946,000 (rounded).
 - The largest research award under the King Program was \$400,000.
- The Bankhead-Coley Program received \$5 million from the DOH which was funded from the tobacco surcharge. These funds were allocated through grants.
 - The total awarded under the Bankhead/Coley Program was \$3,606,000 (rounded).
 - The largest research award under the Bankhead/Coley Program was \$374,000.
- Direct appropriations to institutions.
 - Moffitt received \$5 million from the 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 the 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 the DOH 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.

III. Effect of Proposed Changes:

Section 1 creates s. 381.925, F.S., to establish the Cancer Center of Excellence Award. The award will recognize hospitals, treatment centers, and other providers in Florida that demonstrate excellence in patient-centered, coordinated care for persons undergoing cancer treatment and therapy in this state. The goal is to encourage not only excellence in cancer care in this state, but to attract and retain the best cancer care providers and help Florida to be recognized nationally as a preferred destination for quality cancer care.

The Council and the BRAC will jointly develop rigorous performance measures, a rating system, a rating standard, and an application form that includes submission of documentation that the performance measures have been met. The Council and the BRAC are required to review and jointly revise, if applicable, the performance measures, rating system, and rating standard to ensure providers are continually enhancing their programs to reflect best practices and advances in cancer treatment and care. The performance measures, at a minimum, must require a provider to:

- Maintain a license in Florida that authorizes health care services to be provided. The provider may not have been disciplined or subject to any administrative enforcement action by state or federal regulatory authorities within the preceding three years;

- Be accredited by the Commission on Cancer for the American College of Surgeons;
- Actively participate in at least one regional cancer control collaborative; and
- Meet enhanced cancer care coordination standards which, at a minimum, focus on:
 - Coordination of care by cancer specialists, nurses, and allied health professionals;
 - Psychosocial assessment and services;
 - Suitable and timely referrals and follow-up;
 - Providing accurate and complete information on treatment options that are tailored to the patient's needs, regardless of whether the services are available from that provider;
 - Participation in a comprehensive network of cancer specialists of multiple disciplines so that the patient may consult with various experts to examine treatment alternatives;
 - Family services and support;
 - Aftercare and survivor services; and
 - Patient and family satisfaction survey results.

The DOH will conduct two application cycles annually. The CS provides that the application is not an application for licensure, so the provisions of s. 120.60, F.S., related to licensure do not apply. Also, the state surgeon general's notification to the governor of entities that are eligible for the award is not final agency action, so the provisions in ch. 120, F.S., related to challenges to agency action do not apply.

The state surgeon general will appoint an independent evaluation team from among various groups specified in the bill to determine eligibility for the award. Each application is to be evaluated independently of any other application. Up to two evaluation team members may verify on-site documentation that is submitted with the application. Once each team member has reported the score for the applicants, the state surgeon general will notify the governor regarding the providers that are eligible to receive the Cancer Center of Excellence Award.

A provider who excels in providing quality, comprehensive, and patient-centered coordinated care, as recognized through this program, will be designated as a Cancer Center of Excellence for three years and will be able to use that designation in advertising and marketing, as well as to receive preferential consideration in competitive solicitations by a state agency or state university.

A provider may reapply for subsequent awards.

By January 31, 2014, and annually thereafter, the state surgeon general is required to report to the speaker of the House of Representatives and the president of the Senate on the status of implementing the program, the number of applicants and awards earned, as well as the name of recipients and any recommended legislation to improve the program. The DOH is required to adopt rules for the application cycle and process for the awards.

Section 2 amends s. 215.5602(4), F.S., to include duties related to the Cancer Center for Excellence Award program within the BRAC's responsibilities. Specifically, this requires the BRAC and the Council to develop performance measures, a rating system, a rating standard and an application for the Cancer Center of Excellence Award. The BRAC must provide two members to serve on the evaluation team.

Section 3 amends s. 381.922, F.S., to establish endowments for cancer research institutions in Florida so that the institutions can fund an endowed research chair. Subject to an appropriation, the endowments are to provide a stable funding for a period of at least seven years so that the research institutions are able to recruit and retain experienced and promising researchers. These endowed chairs are to facilitate research coordination among other research institutions within the state and attract other promising researchers and national funding to the state.

If a research institution that has been granted an endowed chair must replace the researcher, the endowment must cease funding expenses associated with the endowed chair, other than reasonable costs for recruitment, until a replacement researcher has been retained. While the chair is vacant, the endowment must continue to earn interest, and all earnings must be added to the endowment balance. A vacancy tolls the seven-year timeframe for the endowed chair.

Any 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 it becomes necessary to replace a research 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 must annually report to the president of the Senate and the speaker of the House of Representatives the name, salary, and specific research responsibilities of the chair, as well as progress toward achieving the goals of the program, and financial information pertaining to the endowment.

The bill provides that the endowment is awarded to the research institution, not to the selected researcher.

Section 4 amends s. 1004.435(4), F.S., to include within the Council's responsibilities, the responsibilities assigned to the Council under the Cancer Center for Excellence Award program. Specifically, this includes requiring the Council and the BRAC to develop performance measures, a rating system, a rating standard, and an application for the Cancer Center of Excellence Award. The bill requires the council to provide three members to serve on the evaluation team.

Section 5 provides an effective date of July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. **Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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 bring their programs to the level contemplated by this bill. Providers receiving the award may be able to secure additional patient revenues as a result of the notoriety of their care.

C. Government Sector Impact:

The bill requires the 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.

VI. **Technical Deficiencies:**

None.

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/CS by Appropriations on March 28, 2013:

The committee substitute provides that:

- The Council and the BRAC are required to review and jointly revise, if applicable, the performance measures, rating system, and rating standard to ensure providers are continually enhancing their programs to reflect best practices and advances in cancer treatment and care.
- If a research institution that has been granted an endowed chair must replace the researcher, the endowment must cease funding expenses associated with the endowed chair, other than reasonable costs for recruitment, until a replacement researcher has been retained. While the chair is vacant, the endowment must continue to earn interest, and all earnings must be added to the endowment balance. A vacancy tolls the seven-year timeframe for the endowed chair.

CS by Children, Families, and Elder Affairs on March 18, 2013:

- The CS changes the responsibility for establishing the application cycles for the Cancer Center of Excellence Award Program from the Council to the DOH and requires the DOH to adopt rules related to the application process.
- The CS provides that the provisions of ch. 120, F.S., do not apply to the application or the notification of eligible entities for the award.
- The CS provides that an application is to be evaluated independently of any other application and documentation may be verified on-site.
- The CS includes, within the Council's responsibilities in the statute establishing the Council and the BRAC's responsibilities in the statute establishing the BRAC, the responsibilities assigned to them under the Cancer Center for Excellence Award program.
- The purpose of the endowment is expanded to provide secure funding for at least 7 years and is not limited to funding the salary of the endowed chair.
- Requires the research institution to report to the governor and the Legislature rather than to the DOH.

B. Amendments:

None.