

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 616

INTRODUCER: Senator Flores

SUBJECT: Biomedical Research

DATE: January 5, 2012

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	O'Callaghan	Stovall	HR	Pre-meeting
2.	_____	_____	GO	_____
3.	_____	_____	BC	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill revises provisions related to the James and Esther King Biomedical Research Program (King Program) and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program).

The bill:

- Carries forward for 2 additional years the balance of any appropriation from the Biomedical Research Trust Fund, which is obligated but not disbursed;
- Renames a member of the Biomedical Research Advisory Council (Council) and the advisory council of the Florida Center for Universal Research to Eradicate Disease (FL CURED);
- Staggers the terms of service for members of the Council;
- Removes the Council's responsibility for developing, supervising, and consulting in the appointment of research peer review panels;
- Clarifies conflict of interest provisions concerning certain councils and peer review panels;
- Removes provisions regarding the public's access to the meetings of certain peer review panels;
- Exempts grant programs under the purview of the Council from rulemaking authority;
- Revises the Council's annual reporting requirement;
- Revises by whom grants are awarded under the Bankhead-Coley Program; and
- Makes the consideration of certain types of applications for grants by the Department of Health (department) discretionary.

This bill amends the following sections of the Florida Statutes: 20.435, 215.5602, 381.855, and 381.922.

II. Present Situation:

The James and Esther King Biomedical Research Program

The purpose of the James and Esther King Biomedical Research Program¹ (King Program) is 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.² The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease;
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use;
- 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 of Florida; and
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The King Program offers competitive grants to researchers throughout Florida. Grant applications from any university or established research institute³ in Florida will be considered for biomedical research funding. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding.

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

- Investigator-initiated research grants;
- Institutional research grants; and

¹ The Florida Legislature created the Florida Biomedical Research Program in 1999 within the department (ch. 99-167, L.O.F.). The Florida Biomedical Research Program was renamed the James and Esther King Biomedical Research Program during Special Session B of the 2003 Legislature (ch. 2003-414, L.O.F.).

² Section 215.5602, F.S.

³ An "established research institute" is any Florida non-profit or foreign non-profit corporation covered under ch. 617, F.S., with a physical location in Florida, whose stated purpose and power is scientific, biomedical or biotechnological research or development and is legally registered with the Florida Department of State, Division of Corporations. This includes the federal government and non-profit medical and surgical hospitals, including veterans' administration hospitals. See James & Esther King Biomedical Research Program, *Call for Grant Applications: Biomedical, Biotechnological, and Social Scientific Research and Development, Fiscal Year 2009-2010*, page 7, available at: http://forms.floridabiomed.com/jek_call/King%20Call%2009-10.pdf (Last visited on January 5, 2012).

⁴ See the "Grant Application Review and Processing" section of Senate Interim Report 2010-219, page 7, for more information about assessing scientific merit. The report is available at: http://archive.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-219hr.pdf (Last visited on January 5, 2012).

- Predoctoral and postdoctoral research fellowships.⁵

The King Program was to expire on January 1, 2011, pursuant to s. 215.5602, F.S. However, the Legislature continued the program in 2010 by enacting HB 5311.⁶

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

The 2006 Legislature created the Bankhead-Coley Program within the department.⁷ The purpose of the program is to advance progress toward cures for cancer through grants awarded for cancer research.

Applications for funding cancer research from any university or established research institute in the state will be considered under the Bankhead-Coley Program. All qualified investigators in the state, regardless of institutional affiliation, have equal access and opportunity to compete for the research funding. The State Surgeon General, after consultation with the Council, is authorized to award grants and fellowships on the basis of scientific merit⁸ within the following three categories:

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

As with the King Program, the Bankhead-Coley Program was to expire on January 1, 2011, pursuant to s. 215.5602, F.S. However, the Legislature also continued this program in 2010 when it enacted HB 5311.⁹

Florida Center for Universal Research to Eradicate Disease

The purpose of the Florida Center for Universal Research to Eradicate Disease (FL CURED) is to coordinate, improve, expand, and monitor all biomedical research programs within Florida; facilitate funding opportunities; and foster improved technology transfer of research findings into clinical trials and widespread public use.¹⁰

The Legislature intended that the FL CURED would help Florida:

- Strive to become the nation’s leader in biomedical research;
- Commit to finding cures for the most deadly and widespread diseases;
- Coordinate efforts among the state’s public and private universities and research institutes, and the biomedical/biotechnology industry in Florida; and

⁵ Section 215.5602(5)(b), F.S.

⁶ Chapter 2010-161, L.O.F.

⁷ Section 381.922, F.S., (ch. 2006-182, L.O.F.).

⁸ *Supra* fn. 5.

⁹ Chapter 2010-161, L.O.F.

¹⁰ *See* s. 381.855, F.S.

- Expand the economy by attracting biomedical researchers and biotechnology businesses to the state.¹¹

Responsibilities of the FL CURED are to hold an annual biomedical technology summit in Florida, encourage clinical trials in Florida, facilitate research partnerships, encourage agricultural colleges and agricultural businesses in Florida to be active in the search for cures and in providing information to the public about disease prevention, encourage the discovery and production in Florida of vaccines that prevent disease, monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research, serve as a registry for all biomedical grants, and maintain a website with links to peer-reviewed biomedical research.¹²

Within the FL CURED is a 15-member advisory council that meets at least annually.¹³

Program Funding

Initially, the King Program was funded with income from \$150 million of principal in the Lawton Chiles Endowment Fund.¹⁴ In 2004, the Legislature appropriated additional funding, through a distribution from alcoholic beverage surcharge taxes. In 2006, the Legislature substituted a \$6 million dollar annual appropriation commitment from the General Revenue Fund to fund the Biomedical Research Trust Fund within the DOH for the purposes of the King Program.¹⁵ However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the King Program was reduced to \$4.5 million.¹⁶ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the King Program for the 2009-2010 fiscal year.¹⁷

In 2010, when the Legislature reenacted the King Program, it continued funding for the King Program with an annual appropriation of \$20 million.¹⁸ Of the funds appropriated for the King Program, up to \$250,000 per year is designated to operate the FL CURED.

The Bankhead-Coley Program was established with a commitment for an appropriation of \$9 million per year from the General Revenue Fund.¹⁹ However, in the January 2009 Special Session A, for fiscal year 2008-2009 and each fiscal year thereafter, the annual appropriation from the General Revenue Fund to the Biomedical Research Trust Fund for purposes of the

¹¹ Florida Center for Universal Research to Eradicate Disease, FL CURED, *2010 Annual Report*, p. V, Executive Summary, available at: <http://flcured.org/docs/AnnualReport2010.pdf> (Last visited on January 5, 2012).

¹² Section 381.855, F.S.

¹³ *Id.*

¹⁴ Section 215.5601, F.S. The Lawton Chiles Endowment Fund's principal originated from a portion of the state settlement received from its lawsuit with tobacco companies.

¹⁵ Chapter 2006-182, L.O.F.

¹⁶ Chapter 2009-5, L.O.F.

¹⁷ Chapter 2009-58, L.O.F.

¹⁸ *Supra* fn. 11.

¹⁹ Section 381.922(5), F.S.

Bankhead-Coley Program was reduced to \$6.75 million.²⁰ During the regular session in 2009, the Legislature eliminated the general revenue appropriation and provided that 2.5 percent of the revenue generated from the additional cigarette surcharge enacted in 2009, not to exceed \$25 million, was to be transferred into the Biomedical Research Trust Fund for the Bankhead-Coley Program.²¹

Chapter 2009-58, Laws of Florida, provided that five percent of the revenue deposited into the Health Care Trust Fund pursuant to s. 210.011(9), F.S., related to the cigarette surcharge and s. 210.276(7), F.S., related to the surcharge on tobacco products, are to be reserved for research of tobacco-related or cancer-related illnesses. The sum of the revenue reserved, however, may not exceed \$50 million in any fiscal year. The Legislature did not specify an amount to be appropriated annually, after the 2009-2010 fiscal year, for the King Program or the Bankhead-Coley Program from these reserves. However, in 2010, when the Legislature reenacted the Bankhead-Coley Program along with the King Program, it continued funding for the Bankhead-Coley Program with an annual appropriation of \$20 million.²²

Any cash balance in the Biomedical Research Trust Fund at the end of a fiscal year remains in the trust fund to be available for carrying out the purposes of the trust fund. In addition, any balance of an appropriation from the Biomedical Research Trust Fund which has not been disbursed, but which is obligated, may be used for up to 3 years from the effective date of the original appropriation.

Biomedical Research Advisory Council²³ and Peer Review Panel²⁴

The purpose of the Council is to advise the State Surgeon General as to the direction and scope of the King Program. The Council is also required to consult with the State Surgeon General concerning grant awards for cancer research through the Bankhead-Coley Program.²⁵ Currently there are 11 members on the council, authorized to serve no more than two consecutive, 3-year terms.

In order to ensure that proposals for research funding within the King Program and the Bankhead-Coley Program are appropriate and evaluated fairly on the basis of scientific merit, a peer review panel of independent, scientifically qualified individuals is appointed to review the scientific content of each proposal to establish a “scientific”²⁶ priority score.²⁷ To eliminate conflicts of interest, peer reviewers come from outside the state of Florida. Reviewers are experts in their fields from universities, government agencies, and private industry who are matched according to application topic and area of expertise. The priority scores must be considered by

²⁰ Chapter 2009-5, L.O.F.

²¹ Chapter 2009-58, L.O.F.

²² *Supra* fn. 11.

²³ Section 215.5602(3), F.S.

²⁴ Section 215.5602(6) and (7), and s. 381.922(3)(b), F.S.

²⁵ Section 381.922(3)(a), F.S. However, s. 215.5602(11), F.S., contains an inconsistency with respect to the responsibility of the Council concerning awarding grants for cancer research.

²⁶ The King Program requires a *scientific* priority score in s. 215.5602(6), F.S. The Bankhead-Coley Program requires a priority score in s. 381.922(3)(b), F.S.

²⁷ A Bridge Grant application is ranked solely by the priority score or percentile assigned to its qualifying federal proposal in an eligible federal review process.

the Council in determining which proposals will be recommended for funding to the State Surgeon General.

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

Program Administration and Grant Management

The Office of Public Health Research within the DOH manages both the King Program and the Bankhead-Coley Program with support from the Council and Lytmos Group, LLC (Lytmos), pursuant to contract.²⁸

The law authorizes, but does not require, the department, after consultation with the Council, to adopt rules as necessary to implement these programs.²⁹ The department has not adopted rules to implement these programs. Instead, the department publishes, on its website, the procedures for implementing these two programs.³⁰

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

III. Effect of Proposed Changes:

Section 1 amends s. 20.435, F.S., to extend the time, from 3 years to 5 years, that any balance of any appropriation from the Biomedical Research Trust Fund, which is not disbursed but which is obligated pursuant to a contract or committed to be expended, may be carried forward after the effective date of the original appropriation.

Section 2 amends s. 215.5602, F.S., to replace the member of the Council, who is the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, with the chief executive officer of the Greater Southeast Affiliate of the American Heart Association.³¹ This section also provides for staggered terms of members on the Council by requiring the first two appointments by the Governor and the first appointment by the President of the Senate and the Speaker of the House of Representatives on or after July 1, 2012, to be for a term of 2 years.

²⁸ James & Esther King Biomedical Research Program, *Annual Report 2010*, available at: <http://forms.floridabiomed.com/AnnualReports/Annual10.pdf> (Last visited on January 5, 2012).

²⁹ Section 215.5602(9), F.S.

³⁰ See <http://www.doh.state.fl.us/ExecStaff/biomed/ophrsitemap.html>, (Last visited on January 5, 2012).

³¹ The following states and territories are part of the Greater Southeast Affiliate: Alabama, Florida, Georgia, Louisiana, Mississippi, Puerto Rico, and Tennessee. American Heart Association, *Who We Are: Greater Southeast Affiliate*, available at: http://www.heart.org/HEARTORG/Affiliate/Who-We-Are-Greater-Southeast-Affiliate_UCM_303250_SubHomePage.jsp (Last visited on January 5, 2012).

In this section, the Council's authority to develop and supervise research peer review panels is removed. Furthermore, the department, rather than the Surgeon General, is no longer required to consult with the Council prior to appointing a peer review panel to review the scientific *merit* of research proposals.

This section clarifies that a member of the Council or peer review panel may not participate in any discussion or decision *of the Council or panel*, with respect to a research proposal by an entity with which the member is associated, employed, or contracted, to avoid a conflict of interest.

This section removes the provision that specifies that meetings of the peer review panel are subject to Florida's public records laws. However, by operation of ch. 119, F.S., s. 286.011, F.S., and s. 24, Art. I of the State Constitution, the peer review panel would still be subject to such public record laws.

This section also exempts grant programs under the purview of the Council from rulemaking authority under ch. 120, F.S., and removes the department's rulemaking authority to implement the section.

This section amends the Council's requirement to submit an annual progress report to the Governor, the State Surgeon General, and the Legislature to require the report to review, for each fiscal year, all programs under the Council's purview. The report is required to be submitted annually by December 15, instead of by February 1. The reporting requirement is also changed to require the Council to include in its annual report the state ranking from the National Institutes of Health, rather than a broader requirement for the total amount of biomedical research funding currently flowing into the state from any source; the progress toward the program's goals; and recommendations that further the program's mission.

Section 3 amends s. 381.855, F.S., to specify that the member of the advisory council of the FL CURED from the American Heart Association must be from the Greater Southeast Affiliate.

Section 4 amends s. 381.922, F.S., to require grants to be awarded by the department, instead of the State Surgeon General. In addition, the requirement for the Surgeon General to consult with the Council prior to awarding a grant is removed.

This section authorizes, rather than requires, the department to consider certain types of applications for funding. This section clarifies that the peer review panel is to review the scientific merit, not content, of each research proposal and establish its priority score for the Council to consider.

This section clarifies that a member of the Council or peer review panel may not participate in any discussion or decision *of the Council or panel*, with respect to a research proposal by an entity with which the member is associated, employed, or contracted, to avoid a conflict of interest.

This section removes the provision that specifies that meetings of the peer review panel are subject to Florida's public records laws. However, by operation of ch. 119, F.S., s. 286.011, F.S.,

and s. 24, Art. I of the State Constitution, it is likely that the peer review panel would still be subject to such open meetings and public records laws.

This section deletes the department's annual reporting requirement to the Governor and Legislature, which requires the department to report the progress toward the Bankhead-Coley Program's mission and make recommendations to further the program's purpose. Instead, this requirement is added to section 2 of the bill.

Section 5 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Council may realize some cost-savings because it no longer is required to develop and supervise research peer review panels.

VI. Technical Deficiencies:

Line 142 of the bill requires the department, instead of the State Surgeon General, to appoint a peer review panel and deletes the requirement that the State Surgeon General consult with the Council prior to appointing the panel. Line 239 of the bill retains the requirement that the State Surgeon General, in consultation with the Council, is to appoint a peer review panel. If it is the intent for the panel appointment procedure in line 239 to align with the panel appointment

procedure in line 142 of the bill and the revised responsibilities of the Council, then line 239 should be amended to correspond with the language in line 142 of the bill.

VII. Related Issues:

Although lines 157-159 and 254-256 delete the affirmative statement that meetings of the peer review panel are subject to Florida's public record laws, such meetings are likely to be subject to Florida's open meetings and public records laws by operation of law, notwithstanding striking this provision.

Florida's Government in the Sunshine Law (Sunshine Law), under s. 286.011, F.S., is equally applicable to elected and appointed boards and applies to any gathering of two or more members of the same board to discuss some matter which will foreseeably come before that board for action.³²

The three basic requirements of s. 286.011, F.S., are that meetings of public boards or commissions must be open to the public, reasonable notice of such meetings must be given, and minutes of the meetings must be taken. Under s. 24, Art. I of the Florida Constitution, virtually all collegial public bodies are covered by the open meetings mandate, with the exception of the judiciary and the state Legislature.³³

Advisory bodies created pursuant to law are subject to the Sunshine Law, even though their recommendations are not binding upon the entities that create them.³⁴ If the advisory body conducts only fact-finding and has no decision-making function, then it may be exempt from the Sunshine Law.³⁵

The bill requires the department and the State Surgeon General to each appoint a peer review panel and each panel is required to prioritize research proposals to recommend the funding of such proposals. Because the panels are created by law, appointed by an agency, and do more than merely fact-finding, it is likely that the panels would be deemed subject to Florida's Sunshine Law.

As for the peer review panels' meeting materials and records, they are likely to be subject to Florida's public records law under ch. 119, F.S., because all materials made or received by an agency³⁶ in connection with official business, which are used to perpetuate, communicate, or formalize knowledge are required to be open to public inspection unless the Legislature specifically exempts them from disclosure. Omitting the peer review panel meetings from the statement that such meetings are subject to Florida's open meetings and public records laws is not likely to constitute an exemption by the Legislature. The Legislature must pass a separate bill by a two-thirds vote of each house to enact a public records or public meeting exemption, and the

³² Government-in-the-Sunshine Manual, Volume 30, 2008 Edition, p. 5.

³³ *Id.*

³⁴ *Id.* at p. 6.

³⁵ *Id.* at p. 7.

³⁶ Advisory boards or committees have been interpreted in case law and by the Attorney General's Office to be subject to the public records law. Government-in-the-Sunshine Manual, Volume 30, 2008 Edition, p. 63.

law must state with specificity the public necessity justifying the exemption, which must be no broader than necessary to accomplish the stated purpose of the law.³⁷

SB 1856 has been filed, which also removes the provision that specifies that meetings of the peer review panel are subject to Florida's public records laws, and provides a public necessity statement. However, in order for a bill to exempt a record or meeting from the public records or meetings laws it must state that the record or meeting is:

- Exempt from s. 24, Art. I of the State Constitution;
- Exempt from s. 119.07(1) or s. 286.011, F.S.; and
- Repealed at the end of 5 years and that the exemption must be reviewed by the Legislature before the scheduled repeal date.³⁸

Therefore, SB 1856, is likely still not sufficient to make meetings or records of the peer review panel confidential and exempt from Florida's public records and meetings laws.

VIII. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

³⁷ FLA. CONST. art. I, s. 24(c).

³⁸ Section 119.15(4)(a), F.S.