

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 655 Biomedical Research
SPONSOR(S): Health & Human Services Committee; Coley
TIED BILLS: HB 657 **IDEN./SIM. BILLS:** SB 616

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Access Subcommittee	15 Y, 0 N	Holt	Schoolfield
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee	17 Y, 0 N, As CS	Holt	Gormley

SUMMARY ANALYSIS

The James and Esther King Biomedical Research Program and William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program award competitive grants and fellowships for biomedical research. The grants are awarded based on criteria and standards developed by the Biomedical Research Advisory Council (Council) and are reviewed by independent peer review panels. The bill makes operational changes to both programs; but does not alter the appropriations to either program.

The bill exempts grant programs under the purview of the Council from the Administrative Procedures Act pursuant to Chapter 120, F.S. The bill makes conforming changes by deleting the requirement that the Council and peer review panels are subject to public records and meeting requirements. The bill adjusts the membership appointment terms to the Council allowing for staggered terms and allows one of the two House appointees to the Biomedical Research Advisory Council to be from a comprehensive cardiovascular program with experience in biomedical research approved by the College of Cardiology. The bill strikes permissive language outlining the responsibilities of the Council, such that the Council will no longer be responsible for "developing and supervising research peer review panels". The bill provides the Council flexibility by allowing it to solicit applications for any of the three types of research grants allowed every funding cycle. The bill increases the amount of time any balance that is not dispersed from the Biomedical Research Trust Fund within DOH may carry forward from three to five years.

The bill consolidates duplicative annual progress reports submitted by the King Program and the Bankhead-Coley Program into one report that requires a fiscal-year progress report of program activities and changes the date that the report must be submitted from February 1 to December 15. The bill requires that the progress report include: the state ranking received from the National Institutes of Health and recommendations to further the programs mission. The bill updates the name of an organization that sits on the Council and FL CURED from the Florida/Puerto Rico Affiliate of the American Heart Association to the Greater Southeast Affiliate of the American Heart Association.

The bill has no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Biomedical Research Programs

The 1999 Legislature established the Lawton Chiles Endowment Fund as a result of its settlements with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, Florida Statutes, establishes the James and Esther King Biomedical Research Program (King Program) within the Department of Health (DOH) funded from interest earnings on the endowment fund, tobacco surcharge, and General Revenue Fund.¹ The funds appropriated to the program are devoted to awarding competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease.

In 2004, the Legislature created the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program).² The Bankhead-Coley Program is established within DOH and is funded by an annual appropriation from the General Revenue Fund.³ The purpose of the Bankhead-Coley Program is to advance progress towards cures for cancer and cancer-related illnesses through grants awarded through a peer-reviewed process.

Also in 2004, the Legislature created the Florida Center for Universal Research to Eradicate Disease (FL CURED).⁴ The purpose of FL CURED is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.⁵

The research grants and fellowships for biomedical research are awarded based on criteria and standards developed by the Biomedical Research Advisory Council (Council) created within DOH and reviewed by independent peer review panels.⁶ The Council is directed to award grants for the King Program and the Bankhead-Coley Program.

The Council consists of eleven members:⁷

- Chief Executive Officer of the Florida Division of the American Cancer Society, or designee;
- Chief Executive Officer of the Florida/Puerto Rico Affiliate of the American Heart Association or designee;
- Chief Executive Officer of the American Lung Association of Florida or designee;
- Four Governor appointees, of which, two members must have expertise in the field of biomedical research; a member from an in-state research university; and a member representing the general population of the state;
- Two Senate appointees, of which, a member possessing expertise in the field of behavioral or social research and a member representing a cancer program approved by the American College of Surgeons; and
- Two House appointees, of which, a member from a professional medical organization, and a member representing a cancer program approved by the American College of Surgeons.

¹ Section 215.5602(1) and (12), F.S.

² Chapter 2004-2, L.O.F.

³ Section 215.5602(12), F.S.

⁴ Chapter 2004-2, L.O.F.

⁵ Section 381.855(1), F.S.

⁶ Sections 215.5602(3) and 381.922(3)(b), F.S.

⁷ Section 215.5602(3), F.S.

The Council is to advise the State Surgeon General as to the direction and scope of the biomedical research program in addition to:⁸

- Providing advice on program priorities and emphases;
- Providing advice on the overall program budget;
- Participating in periodic program evaluation;
- Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program;
- Assisting in the development of linkages with other private and public entities and officials;
- Developing criteria and standards for the award of research grants;
- Developing administrative procedures for the solicitation, reviewing and awarding of grants and fellowships to ensure impartial, high-quality peer review system;
- Developing and supervising research peer review panels;
- Reviewing reports of peer review panels and making recommendations for grants and fellowships;
- Developing and providing oversight regarding mechanisms to disseminate research results.

Members of the council are to serve without compensation, but may receive reimbursement for travel and other necessary expenses incurred in the performance of their official duties.

The Council is required to submit an annual progress report on the state of biomedical in this state to the Florida Center for Universal Research to Eradicate Disease (FL CURED) and to the Governor, the State Surgeon General, and the Speaker of the House of Representatives by February 1. The report must include:⁹

- A list of research projects awarded;
- A list of recipients;
- A list of publications supported awards;
- The total amount of biomedical research funding currently flowing into the state;
- New grants that were funded based on research supported by awarded grants or fellowships; and
- Progress in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

The independent peer review panel is required to evaluate three types of awards:

- Investigator-initiated research grants;
- Institutional research grants;
- Predoctoral and postdoctoral research fellowships.

The award applications are reviewed on the basis of scientific merit to ensure that all proposals for research funding are appropriate and are evaluated fairly.¹⁰ The peer review panel process reviews the content of each proposal and establishes a scientific priority score. The priority score is considered in the review process by the Council who makes a recommendation to the State Surgeon General as to what grants or fellowships should be awarded. The Council and peer review panels are directed to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest.¹¹

Sections 215.5602(7) and 381.922(3)(c), F.S., provides that the meetings of the Council and the peer review panels are subject to the public records and public meetings requirements.

⁸ Section 215.5602(4), F.S.

⁹ Section 215.5602(10), F.S.

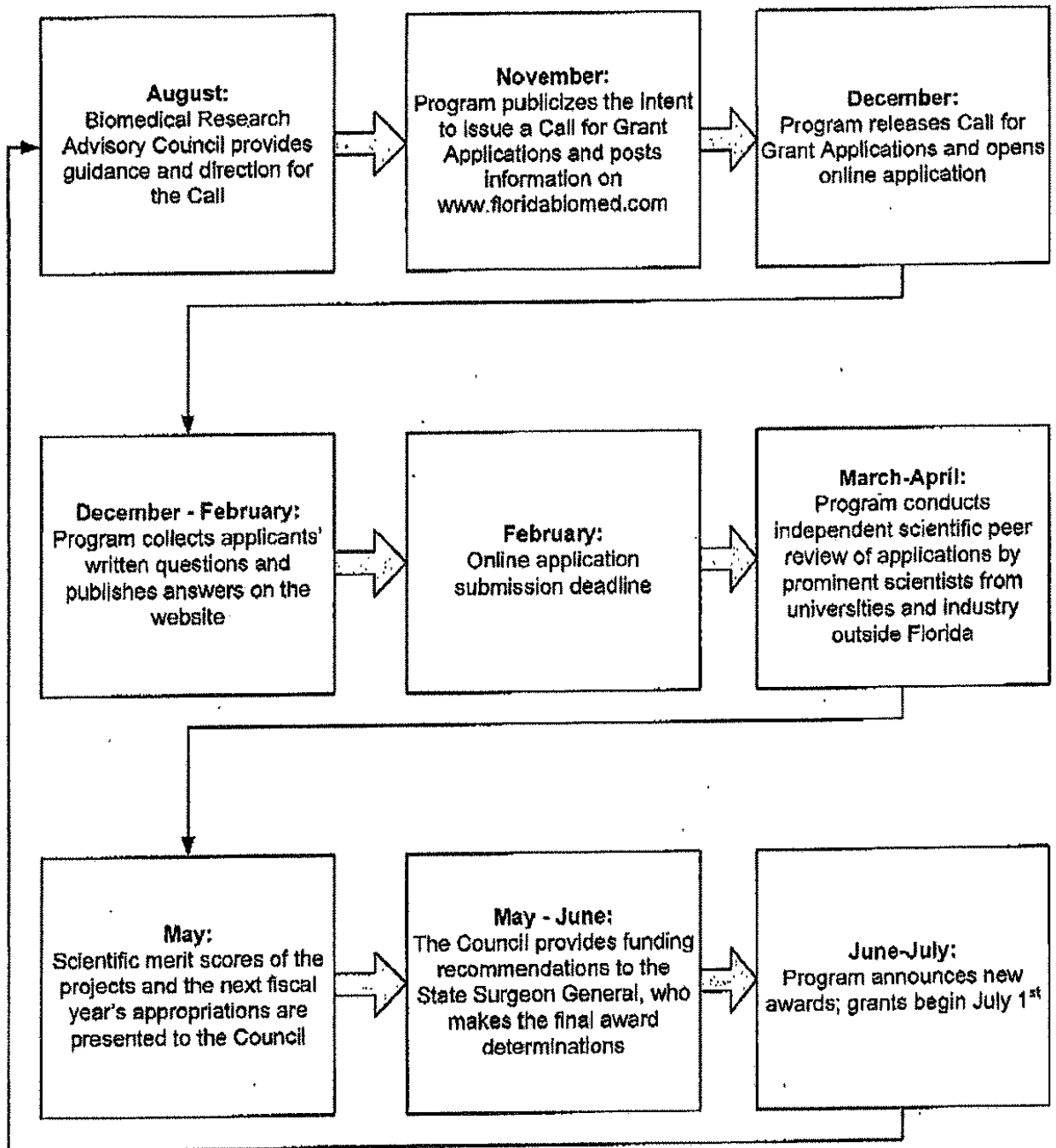
¹⁰ Sections 215.5602(6) and 381.922(3)(b), F.S.

¹¹ Sections 215.5602(7) and 381.922(3)(c), F.S.

Annual Grant Funding Cycle

The annual funding cycle for the King and Bankhead-Coley Programs take 12-months to complete.¹² The Call for Grant Applications (the Call) is usually done once per year in December, but may occur more frequently. Having the Call in December, allows researchers time to write their proposals and for DOH to convene peer-review panels and present the results of the Call to the Advisory Council by May after the state budget is passed.

The James & Esther King and Bankhead-Coley Research Programs Annual Grant Funding Cycle



¹² Per letter from DOH staff dated September 21, 2009 on file with Health & Human Services Access Subcommittee staff.

Effects of Proposed Changes

The bill adjust the membership appointment terms to the Council allowing for staggered terms, such that the first two Governor appointees, and the first Senate and House appointees made on or after July 1, 2012 are for a term of two years instead of three years. The bill updates the name of an organization that sits on the Council and FL CURED from the Florida/Puerto Rico Affiliate of the American Heart Association to the Greater Southeast Affiliate of the American Heart Association. The bill allows one of the two House appointees to the Council to be from a comprehensive cardiovascular program with experience in biomedical research approved by the College of Cardiology. According to DOH, Council member appointments tend to run in parallel, resulting in multiple members rotating off of the Council at the same time.¹³

The bill strikes permissive language outlining the responsibilities of the Council, such that the Council will no longer be responsible for “developing and supervising research peer review panels”. According to DOH, Council members intentionally do not have any contact with peer review panels in order to avoid any real or perceived conflict of interest, or allegations of bias or undue influence and believe that a separation between the peer review panels and the Council is the best practice for merit-based, independent grant review.¹⁴ The bill reassigns the duty of appointing peer review panel membership from being the responsibility of the State Surgeon General in consultation with the Council to being the responsibility of DOH. According to DOH, recruiting and assigning peer reviewers is a function and awarded through the competitive bid process to a professional grant management services vendor.¹⁵ Furthermore, neither the Council nor the State Surgeon General has direct involvement in selecting a peer reviewer and utilizing an outside vendor avoids any real or perceived conflict of interest, or allegations of bias or undue influence.

The bill provides flexibility as to the type of grants that may be awarded. Currently, the Council is required to consider funding three types of research grants: investigator-initiated, institutional, and pre-doctoral and postdoctoral fellowships. According to DOH, traditionally pre-and postdoctoral fellowships are not recommended for funding because support is already provided through current funding practices (i.e., senior investigators receive funding and hire pre-and postdoctoral fellows to assist with projects.) The bill allows the Council to solicit applications for one or any combination of the three types of research grants every funding cycle.

The bill increases the amount of time any balance that is not dispersed from the Biomedical Research Trust Fund within DOH may carry forward from 3 to 5 years. According to DOH, this will allow them to offer longer grant periods to researchers enabling them to conduct clinical trials that are more likely to result in a marketable product and is consistent with grant timeframes seen in other research programs such as the National Institutes of Health.¹⁶ In Fiscal Year 2010-2011, approximately \$25.2M in the Biomedical Research Trust Fund was carried forward.¹⁷

The bill adds language stating that grant programs under the purview of the Council are exempt from the Administrative Procedures Act pursuant to Chapter 120, F.S. The bill strikes language stating that the meetings of the Council and the peer review panels are subject to the public meetings requirements. These two changes conforms the bill with the tied public records bill HB 657, which provides a public records and meeting exemption for peer review panels when biomedical research grants and applications are discussed and reviewed.

¹³ Department of Health, Bill Analysis, Economic Statement and Fiscal Note, House Bill 655, dated December 21, 2011, on file with Health & Human Services Access Subcommittee staff.

¹⁴ *Id.*

¹⁵ DOH has a 3-year contract the Lytmos Group, LLC, for \$8.3M that expires September 30, 2013. Email correspondence with DOH budget staff on file with Health & Human Services Access Subcommittee staff.

¹⁶ Department of Health, Bill Analysis, Economic Statement and Fiscal Note, House Bill 655, dated December 21, 2011, on file with Health & Human Services Access Subcommittee staff.

¹⁷ Email correspondence with DOH budget staff dated January 5, 2012, on file with Health & Human Services Access Subcommittee staff.

The bill removes permissive language granting DOH the authority to adopt rules. According to DOH, the program has operated without a rule since 2007, because current law provides permissibility to the department to adopt rules.¹⁸ Current law states, "The department, after consultation with the council, may adopt rules as necessary to implement this section."¹⁹ In 2007, DOH repealed ch. 64H-1.001, F.A.C. Additionally, the Council prefers to operate without rules to assure flexibility in the grant process allowing them to respond quickly to changing research priorities at the federal level in order to maximize the state's ability to compete for federal grants.²⁰

The bill consolidates duplicative annual progress reports submitted by the King Program and the Bankhead-Coley Program into one report that requires a fiscal-year progress report of program activities and changes the date that the report must be submitted from February 1 to December 15. The bill requires that the progress report include the state ranking received from the National Institutes of Health and recommendations to further the programs mission.

B. SECTION DIRECTORY:

Section 1. Amends s. 20.435, F.S., relating to Department of Health trust funds.

Section 2. Amends s. 215.5602, F.S., relating to the James and Esther King Biomedical Research Program.

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

Section 4. Amends s. 381.855, F.S., relating to Florida Center for Universal Research to Eradicate Disease.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None identified.

2. Expenditures:

None identified.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None identified.

2. Expenditures:

None identified.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

¹⁸ *Id.*

¹⁹ Section 215.5602(9), F.S.

²⁰ *Id.*

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 provides an exemption to the grant programs under the purview of the Council from the rule-making requirements of chapter 120, F.S., the Administrative Procedures Act. This bill is tied to a public records bill, House Bill 657, which provides an exemption from public records and public meeting required by chapter 120, F.S., for peer review panels.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 16, 2012, the Health & Human Services Committee adopted a strike-all amendment and an amendment to the amendment and reported the bill favorably as a committee substitute. The strike-all:

- Makes conforming changes to the Bankhead-Coley program to match changes to the King program by deleting the authority for the Surgeon General to appoint peer review panels and award grants and transferring the authority to DOH;
- Makes conforming changes to both programs by deleting two references to public meetings and public records, which are stricken in HB 657 the tied public records bill; and
- Amends language to makes terminology usage consistent and improve readability.

The amendment to the amendment allows one of the two House appointees to the Biomedical Research Advisory Council to be from a comprehensive cardiovascular program with experience in biomedical research approved by the College of Cardiology.

This analysis is drafted to the committee substitute.