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By the Committees on Higher Education; Health Regulation; and Health Regulation; and Senator Detert

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A bill to be entitled

An act relating to biomedical research programs; amending s. 215.5602, F.S.; deleting provisions requiring that the James and Esther King Biomedical Research Program be funded by proceeds from the Lawton Chiles Endowment Fund; modifying the terms and membership and establishing a staggered membership for appointed members of the Biomedical Research Advisory Council; authorizing the Biomedical Research Advisory Council to recommend a portion of the allocation for the James and Esther King Biomedical Research Program for specified purposes and to develop a grant application and review mechanism; prohibiting any member of the council from participating in discussions or decisions regarding certain proposals; reducing the percentage of funds available for administrative expenses of the James and Esther King Biomedical Research Program; requiring the Department of Health to adopt rules to administer the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; increasing the funding available to the Florida Center for Universal Research to Eradicate Disease; allocating a specified amount of money to the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; authorizing the Department of Health to accept and use gifts for awards under the James and Esther King Biomedical

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Research Program; deleting obsolete provisions; deleting a provision providing for the future expiration of the James and Esther King Biomedical Research Program; amending s. 381.855, F.S.; revising the membership of the advisory council within the Florida Center for Universal Research to Eradicate Disease; repealing s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force; repealing s. 381.92, F.S., relating to the Florida Cancer Council; repealing s. 381.921, F.S., relating to the mission and duties of the Florida Cancer Council; amending s. 381.922, F.S.; revising the purpose of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; revising the duties and goals of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; revising the types of applications considered for funding; authorizing the Biomedical Research Advisory Council to recommend a portion of the allocation for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program for specified purposes and to develop a grant application and review mechanism; prohibiting any member of the council from participating in discussions or decisions regarding certain proposals; requiring the department to submit to the Governor and Legislature a report by a specified date; providing a funding source for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; reducing the percentage of funds available for administrative expenses of the

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William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; authorizing the Department of Health to accept and use gifts for awards under the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; deleting obsolete provisions; deleting provisions providing for the future expiration of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; creating s. 381.923, F.S., relating to the Florida Comprehensive Cancer Control Act; providing a short title; providing legislative intent; providing definitions; creating the Florida Cancer Control and Resource Advisory Council; providing membership of the council; providing the composition of the executive committee of the council; providing for terms of the council and meetings; providing for reimbursement for per diem and travel expenses; prohibiting a member of the council from participating in any discussion or decision to recommend any type of award or contract to any qualified nonprofit association or to any agency of this state or its political subdivisions with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement; providing the duties and responsibilities of the council; requiring the council to report findings and recommendations to the Governor, the Legislature, and the State Surgeon General; requiring the council to develop or purchase written summaries regarding medically viable treatment

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alternatives for the management of breast cancer and prostate cancer; providing requirements for the written summaries; requiring the council to develop and implement education programs regarding early detection and treatment of breast cancer and prostate cancer; requiring that the H. Lee Moffitt Cancer Center and Research Institute, Inc., provide an executive director for the council; allocating a specified amount of money from the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program to the H. Lee Moffitt Cancer Center and Research Institute, Inc., for administrative costs and staff support; authorizing the Department of Health to administer the act; requiring the department to produce the Florida Cancer Plan in consultation with the Florida Cancer Control and Resource Advisory Council; creating the Cancer Control Collaborative Program within the Department of Health; providing the responsibility and mission of the program; requiring the department to appoint a director; providing duties for each collaborative; requiring the collaborative program to submit to the Florida Cancer Control and Resource Advisory Council an annual report by a specified date; requiring the Cancer Control Collaborative Program to serve as the infrastructure for expansion or adaption as federal programs or other opportunities arise for future cancer control initiatives; amending ss. 458.324 and 459.0125, F.S.; conforming cross-references; repealing s. 1004.435,

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F.S., relating to cancer control and research; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 215.5602, Florida Statutes, is amended to read:

215.5602 James and Esther King Biomedical Research Program.—

- (1) There is established within the Department of Health the James and Esther King Biomedical Research Program funded by the proceeds of the Lawton Chiles Endowment Fund pursuant to s. 215.5601. The purpose of the James and Esther King Biomedical Research Program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobaccorelated cancer, cardiovascular disease, stroke, and pulmonary disease. The long-term goals of the program are to:
- (a) Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
- (b) 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.
- (c) 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.
  - (d) Increase the state's per capita funding for research by

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undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.

- (e) Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.
- (2) Funds appropriated for the James and Esther King Biomedical Research Program shall be used exclusively for the award of grants and fellowships as established in this section; for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease; and for expenses incurred in the administration of this section; and as provided in subsections (5) and (12). Priority shall be granted to research designed to prevent or cure disease.
- (3) There is created within the Department of Health the Biomedical Research Advisory Council.
- (a) The council shall consist of 13 11 members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Greater Southeast Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of the Southeast Florida, or a designee; the chief executive officer of Enterprise Florida, or a designee; and the chief executive officer of BioFlorida, or a designee. The remaining 8 members of the council shall be appointed as follows:
  - 1. The Governor shall appoint four members, two members

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with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.

- 2. The President of the Senate shall appoint two members, one member with expertise in the field of behavioral or social research and one representative from a cancer program approved by the American College of Surgeons.
- 3. The Speaker of the House of Representatives shall appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.

In making these appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The appointments shall be for 4-year staggered terms a 3-year term and shall reflect the diversity of the state's population. An appointed member may not serve more than two consecutive terms. 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, 2010, shall be for a term of 2 years.

- (b) The council shall adopt internal organizational procedures as necessary for its efficient organization.
- (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

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(d) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties.

- (4) The council shall advise the State Surgeon General as to the direction and scope of the biomedical research program. The responsibilities of the council may include, but are not limited to:
  - (a) Providing advice on program priorities and emphases.
  - (b) Providing advice on the overall program budget.
  - (c) Participating in periodic program evaluation.
- (d) 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.
- (e) Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.
- (f) Developing criteria and standards for the award of research grants.
- (g) Developing administrative procedures relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system.
  - (h) Developing and supervising research peer review panels.
- (i) Reviewing reports of peer review panels and making recommendations for research grants and fellowships.
- (j) Developing and providing oversight regarding mechanisms for the dissemination of research results.

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(5) (a) Applications for biomedical research funding under the program may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for the research funding.

- (b) Grants and fellowships shall be awarded by the State Surgeon General, after consultation with the council, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:
  - 1. Investigator-initiated research grants.
  - 2. Institutional research and training grants.
  - 3. Predoctoral and postdoctoral research fellowships.
- (c) For any given year, the Biomedical Research Advisory
  Council may also recommend up to one-third of the allocation for
  grants by the James and Esther King Biomedical Research Program
  for the recruitment of cancer, heart, or lung researchers and
  research teams to institutions in the state; for operational
  start-up grants for newly recruited cancer, heart, or lung
  researchers and research teams; and for equipment expenditures
  related to the expansion of cancer, heart, or lung research and
  treatment capacity in this state. For the purposes of
  implementing this paragraph, the council may develop a grant
  application and review mechanism other than the process for
  reviewing research proposals prescribed in subsection (6);
  however, such mechanism must ensure a fair and rigorous analysis
  of the merit of any proposals considered under this paragraph.

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(6) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

- (7) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the council or panel may not participate in any council or panel discussion or decision with respect to a research proposal, or any proposal related to those projects contemplated in paragraph (5)(c), by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.
- (8) The Department of Health may contract on a competitive-bid basis with an appropriate entity to administer the program. Administrative expenses may not exceed 7.5 + 15 = 15 percent of the total funds available to the program in any given year.
- (9) The Department of Health, after consultation with the council, shall may adopt rules as necessary to administer implement this section, taking into consideration the nature of the program and making allowances in any adopted rules which

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enable timely implementation of calls for proposals, proposal reviews, proposal considerations, and any other program activities, and which prevent delays in making annual program awards to grant recipients.

- (10) The council shall submit an annual progress report on the state of biomedical research in this state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by February 1. The report must include:
- (a) A list of research projects supported by grants or fellowships awarded under the program.
  - (b) A list of recipients of program grants or fellowships.
- (c) A list of publications in peer reviewed journals involving research supported by grants or fellowships awarded under the program.
- (d) The total amount of biomedical research funding currently flowing into the state.
- (e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.
- (f) Progress in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
- (11) The council shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922.
- (12) (a) From funds appropriated to accomplish the goals of this section, up to  $\frac{$500,000}{$250,000}$  shall be available for the

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operating costs of the Florida Center for Universal Research to Eradicate Disease.

(b) (a) Beginning in the 2010-2011 2009-2010 fiscal year and thereafter, \$50 million from 5 percent of the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7) shall be reserved for research of tobacco-related or cancer-related illnesses through the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program. The sum of \$25 million shall be allocated annually to each of these programs; however, the sum of the revenue reserved pursuant to ss. 210.011(9) and 210.276(7) may not exceed \$50 million in any fiscal year.

(b) In the 2009-2010 fiscal year, 2.5 percent, not to exceed \$25 million, of the revenue deposited into the Health Care Trust Fund pursuant to this subsection shall be transferred to the Biomedical Research Trust Fund within the Department of Health for the James and Esther King Biomedical Research Program.

unconditionally by will or otherwise, deposit them into the Biomedical Research Trust Fund, and use them for grant or fellowship awards in the James and Esther King Biomedical Research Program. Any gift made under conditions that, in the judgment of the department, upon consultation with the council, are proper and consistent with this section, the laws of the United States, and state law, may be accepted and shall be held, invested, reinvested, and used in accordance with the conditions of the gift. By June 1, 2009, the Division of Statutory Revision

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of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.

(14) The Legislature shall review the performance, the outcomes, and the financial management of the James and Esther King Biomedical Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

(15) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

Section 2. Paragraph (a) of subsection (5) of section 381.855, Florida Statutes, is amended to read:

381.855 Florida Center for Universal Research to Eradicate Disease.—

- (5) There is established within the center an advisory council that shall meet at least annually.
- (a) The council shall consist of one representative from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than \$10 million in annual grant funding from the National Institutes of Health, to be appointed by the State Surgeon General from a different institution each term, and one representative from and appointed by each of the following entities:
  - 1. Enterprise Florida, Inc.
  - 2. BioFlorida.
  - 3. The Biomedical Research Advisory Council.
  - 4. The Florida Medical Foundation.

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including cancer clinical trials projects as provided in this

section, to further the search for cures for cancer; for

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recruiting cancer researchers and research teams to institutions in the state; for operational start-up grants for newly recruited cancer researchers and research teams; or for equipment expenditures related to the expansion of cancer research and treatment capacity in the state.

- (a) Emphasis shall be given to the <u>following</u> goals <u>that are</u> designed to foster dramatic improvement in cancer research capacity in the state enumerated in s. 381.921, as <u>they</u> those goals support the advancement of such cures:
- 1. 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; implement a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state; fund through available resources those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support; encourage 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; facilitate the full spectrum of cancer investigations; facilitate the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and aid in other multidisciplinary research-support activities as they inure to the advancement of cancer research.
- 2. Improve both research and treatment through greater participation in clinical trial networks by:

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<u>a. Identifying ways to increase enrollment in cancer</u> clinical trials;

- b. Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
- c. Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
- d. Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.
- 3. Reduce the impact of cancer on disparate groups by identifying those cancers that disproportionately impact certain demographic groups and building collaborations designed to reduce health disparities as they relate to cancer.
- (b) Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks and the transfer of knowledge gained from research into the practice of community practitioners.
- (3) (a) Applications for funding for cancer research may be submitted by any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Collaborative proposals, including those that advance the program's goals enumerated in subsection (2), may be given preference. Grants

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shall be awarded by the State Surgeon General, after consultation with the Biomedical Research Advisory Council established in s. 215.5602, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

- 1. Investigator-initiated research grants.
- 2. Institutional research and training grants.
- 3. Predoctoral and postdoctoral research fellowships.
- $\underline{4.3.}$  Collaborative research grants, including those that advance the finding of cures through basic or applied research.
- 5. Clinical trial project grants, particularly those projects such as matching services that identify prospective clinical trials treatment options for cancer patients in this state or those projects that otherwise foster greater rates of participation in trials. At least one such grant shall be awarded in any given year if a meritorious proposal or proposals are received. Such project grant proposals are not required to be posed as a research question in order to qualify for an award.
- (b) For any given year, the Biomedical Research Advisory

  Council may recommend up to one-third of the allocation for

  grants by the William G. "Bill" Bankhead, Jr., and David Coley

  Cancer Research Program for the recruitment of cancer

  researchers and research teams to institutions in the state, for

  operational start-up grants for newly recruited cancer

  researchers and research teams, or for equipment expenditures

  related to the expansion of cancer research and treatment

  capacity in the state. For the purposes of implementing this

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paragraph, the council may develop a grant application and review mechanism other than the process for reviewing research proposals prescribed in paragraph (c); however, such mechanism shall ensure a fair and rigorous analysis of the merit of any proposals considered under this paragraph.

(c) (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(d) (e) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the council or panel may not participate in any council or panel discussion or decision with respect to a research proposal, or any proposal related to those projects contemplated in paragraph (b), by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(4) By <u>February 1</u> <u>December 15</u> of each year, the Department of Health shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report

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indicating progress towards the program's mission and making recommendations that further its purpose.

- (5) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program is funded pursuant to s. 215.5602(12) and this section, with an annual allocation of \$25 million. Funds appropriated for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer and cancer-related illnesses, with emphasis given to the goals enumerated in paragraph (2)(a) s. 381.921. From the total funds appropriated, an amount of up to 7.5 10 percent may be used for administrative expenses. In the 2009-2010 fiscal year, 2.5 percent, not to exceed \$25 million, of the revenue deposited into the Health Care Trust Fund pursuant to s. 215.5602(12)(a) shall be transferred to the Biomedical Research Trust Fund within the Department of Health for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
- unconditionally by will or otherwise, deposit them into the Biomedical Research Trust Fund, and use them for grant or fellowship awards in the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program. Any gift made under conditions that, in the judgment of the department, upon consultation with the council, are proper and consistent with this section, the laws of the United States, and state law, may be accepted and shall be held, invested, reinvested, and used in accordance with the conditions of the gift. By June 1, 2009, the Division of Statutory Revision of the Office of Legislative

589-02480A-10 2010620c2 <del>Services shall certify to the President of the Senate and the</del> <del>Speaker of the House of Representatives the language and</del>

554 statutory citation of this section, which is scheduled to expire
555 January 1, 2011.

- (7) The Legislature shall review the performance, the outcomes, and the financial management of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.
- (8) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.
- Section 7. Section 381.923, Florida Statutes, is created to read:
  - 381.923 Comprehensive cancer control.-
- (1) SHORT TITLE.—This section may be cited as the "Florida Comprehensive Cancer Control Act."
- (2) LEGISLATIVE INTENT.—It is the finding of the Legislature that:
- (a) Advances in scientific knowledge have led to prevention, early detection, and therapeutic capabilities in the control of cancer. Such knowledge, screening technologies, and therapies must be made available to all residents of this state.
- (b) Research shows that certain lifestyles and exposures, such as tobacco use, exposure to ultraviolet radiation from the sun, and exposure to occupational and environmental carcinogens, contribute to the risk for many types of cancer and that certain screening tests are effective in finding cancer early when it is more treatable. The role of diet, exercise, and other healthy

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581 <u>lifestyles are also important in cancer prevention and control.</u>
582 <u>Proven causes of cancer and methods for early detection should</u>

- be publicized and be the subject of linguistically and
- 584 <u>culturally appropriate educational and awareness programs for</u>
  585 the prevention of cancer.
  - (c) An effective cancer control program would mobilize the scientific, educational, and medical resources that presently exist into an intense attack against this dreaded disease, with the primary goal to reduce the cancer burden for the residents of this state.
    - (3) DEFINITIONS.—As used in this section, the term:
  - (a) "Cancer" means all malignant neoplasms, regardless of the tissue of origin, including lymphoma and leukemia.
  - (b) "Council" means the Florida Cancer Control and Resource Advisory Council, which is an advisory body appointed to function on a continuing basis to recommend solutions and policy alternatives to the Governor, members of the Legislature, the State Surgeon General, and other policymakers.
    - (c) "Department" means the Department of Health.
    - (d) "Plan" means the Florida Cancer Plan.
  - (e) "Program" means the Florida Cancer Control Collaborative Program.
  - (f) "Qualified nonprofit association" means any association, incorporated or unincorporated, which has received tax-exempt status from the Internal Revenue Service.
  - (4) FLORIDA CANCER CONTROL AND RESOURCE ADVISORY COUNCIL; CREATION; COMPOSITION.—
  - (a) There is created within the H. Lee Moffitt Cancer
    Center and Research Institute, Inc., the Florida Cancer Control

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610 and Resource Advisory Council. The council shall consist of 611 cancer organizational representation and cancer control 612 stakeholders, with a chairperson elected by the council 613 membership for a term of 2 years. Each council member must be a resident of this state. Three members representing the general 614 615 public shall be appointed by the Governor. The Governor shall 616 make three separate appointments for 1-year, 2-year, and 3-year terms beginning July 1, 2010; thereafter, gubernatorial 617 618 appointments to the council shall be for 3-year terms. The 619 President of the Senate and the Speaker of the House of 620 Representatives shall appoint one member from his or her 621 legislative body to serve on the council at any given time. Each 622 of the following organizations shall designate a representative 623 to serve on the council: 624 1. H. Lee Moffitt Cancer Center and Research Institute, 625 Inc. 626 2. University of Florida Shands Cancer Center. 627 3. University of Miami Sylvester Comprehensive Cancer 628 Center. 629 4. Mayo Clinic, Florida. 630 5. M.D. Anderson Cancer Center, Florida. 631 6. American Cancer Society, Florida Division. 632 7. American Lung Association of the Southeast. 633 8. American Association for Retired Persons. 634 9. Department of Health. 635 10. Department of Education. 636 11. Florida Tumor Registrars Association. 637 12. Florida Cancer Data System. 638 13. Florida Society of Oncology Social Workers.

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639 14. Florida Oncology Nurses Society. 640 15. Florida Society of Clinical Oncology. 641 16. Florida Association of Pediatric Tumor Programs, Inc. 642 17. Florida Medical Association. 643 18. Florida Hospital Association. 644 19. Florida Nursing Association. 645 20. Florida Dental Association. 646 21. Florida Osteopathic Association. 647 22. University of Florida College of Medicine. 648 23. University of Miami College of Medicine. 649 24. University of South Florida College of Medicine. 650 25. Florida State University College of Medicine. 651 26. University of Central Florida College of Medicine. 27. Nova Southeastern College of Osteopathic Medicine. 652 653 28. Florida International University College of Medicine. 654 29. Lake Erie School of Osteopathic Medicine. 655 30. Biomedical Research Advisory Council. 656 31. Center for Universal Research to Eradicate Disease. 657 32. A representative from each of the regional Cancer 658 Control Collaboratives. 659 (b) An executive committee, which shall be responsible for 660 coordinating the activities and planning the direction of the full council, shall be comprised of the council's elected 661 662 chairman, one at-large member elected by the full council, and 663 the members representing the Department of Health, the American 664 Cancer Society, the H. Lee Moffitt Cancer Center and Research 665 Institute, Inc., the University of Florida Shands Cancer Center, 666 and the University of Miami Sylvester Comprehensive Cancer 667 Center, as well as the appointee of the President of the Senate,

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the appointee of the Speaker of the House of Representatives, and one of the gubernatorial appointees, who shall be designated by the council's chairman. Should the council chairman be a designee from one of the named entities in this paragraph, the full council shall elect a second at-large position to serve on the executive committee. The elected positions on the executive committee shall be for terms of 2 years.

- (c) The council shall meet at least semiannually. A majority of members shall constitute a quorum for the purpose of exercising all of the powers of the council.
- (d) The council members shall serve without compensation, but are entitled to reimbursement for per diem and travel expenses as provided in s. 112.061.
- (e) A member of the council may not participate in any council discussion or decision to recommend any type of award or contract to any qualified nonprofit association or to any agency of this state or its political subdivisions with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.
- (f) The council may prescribe, amend, and repeal bylaws governing the manner in which the business of the council is conducted.
- (g) The council shall advise the Governor, the Legislature, the State Surgeon General, or other state policymakers with respect to cancer control and resources in this state.
- (h) The council shall approve a plan for cancer control to be known as the "Florida Cancer Plan," which shall be consistent to the extent possible with other cancer or health-related state

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plans and integrated and coordinated with existing programs in this state. The council shall review and approve the plan at least every 2 years.

- (i) The council shall formulate and recommend to the Governor, the Legislature, the State Surgeon General, and other state policymakers a plan for the prevention and early detection of cancer which is evidence-based and consistent with standards of practice and supported by evidence-based medicine. The State Surgeon General and other state policymakers shall consider the plan in developing departmental priorities and funding priorities and standards under chapter 385.
- (j) The council shall provide expertise and input in the content and development of the Florida Cancer Plan.

  Recommendations shall include the coordination and integration of other state plans concerned with cancer control. Committees may be formed by the council so that the following areas will be established as entities for actions:
- 1. Cancer plan evaluation, including tumor registry, data retrieval systems, and epidemiology of cancer in the state and its relation to other areas.
  - 2. Cancer prevention.
  - 3. Cancer detection.
  - 4. Cancer treatments.
  - 5. Support services for cancer patients and caregivers.
  - 6. Cancer education for laypersons and professionals.
  - 7. Other cancer-control-related topics.
- (k) The council shall advise the State Surgeon General on methods of enforcing and implementing laws already enacted and concerned with cancer control.

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(1) The council may recommend to the State Surgeon General rules not inconsistent with law as it may deem necessary for the performance of its duties and the proper administration of this section.

- (m) The council shall be physically located at the H. Lee Moffitt Cancer Center and Research Institute, Inc.
- (n) By December 1 of each year, the council shall report any findings and recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General.
- (o) If funds for this purpose are specifically appropriated by the Legislature, the council shall develop or purchase standardized written summaries, written in layperson's terms and in language easily understood by the average adult patient, informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening of the medically viable treatment alternatives available to them in the effective management of breast cancer and prostate cancer; describing such treatment alternatives; and explaining the relative advantages, disadvantages, and risks associated therewith. The breast cancer summary, upon its completion, shall be printed in the form of a pamphlet or booklet and made continuously available to physicians and surgeons in this state for their use in accordance with s. 458.324 and to osteopathic physicians in this state for their use in accordance with s. 459.0125. The council shall periodically update both summaries to reflect current standards of medical practice in the treatment of breast cancer and prostate cancer. If funds for this purpose are specifically

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appropriated by the Legislature, the council shall develop and implement educational programs, including distribution of the summaries developed or purchased under this paragraph, to inform citizen groups, associations, and voluntary organizations about early detection and treatment of breast cancer and prostate cancer.

- (5) RESPONSIBILITIES OF THE H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC., AND THE DEPARTMENT OF HEALTH.—
- (a) The H. Lee Moffitt Cancer Center and Research
  Institute, Inc., shall provide a full-time executive director to
  coordinate, facilitate, and communicate the mission and
  responsibilities of the council. Additional administrative
  support, information, and other assistance shall also be
  provided as reasonably necessary for the completion of the
  responsibilities of the council.
- (b) From the funds appropriated annually for the William G.
  "Bill" Bankhead, Jr., and David Coley Cancer Research Program,
  the sum of \$150,000 shall be allocated to the H. Lee Moffitt

  Cancer Center and Research Institute, Inc., for the
  administrative costs and staff support to convene and facilitate
  the responsibilities of the council.
- (c) The Department of Health, after consultation with the council, may adopt rules necessary to administer this section.
- (d) The Florida Cancer Plan is established within the Department of Health. The Department of Health shall consult with the council in developing the plan, prioritizing goals, and allocating resources.
- (6) FLORIDA CANCER CONTROL COLLABORATIVE PROGRAM; CREATION; COMPOSITION.—

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(a) The Cancer Control Collaborative Program is established within the Department of Health and resides within the cancer program. The program is responsible for overseeing and providing infrastructure for the state cancer collaborative network. The primary mission of the program is to implement the plan's initiatives and identify and facilitate the local development of solutions to cancer control needs of the populations served by the regional cancer control collaboratives. The Cancer Control Collaborative Program shall prioritize programs and resources to reduce the burden of cancer in this state, consistent with the plan.

- (b) The Department of Health shall appoint a cancer program director, who is responsible for supervising the collaborative program. At a minimum, centralized organization, communications, information technology, shared resources, and cancer control expertise shall be provided to the regional cancer control collaboratives by the Department of Health.
- (c) Each regional cancer control collaborative shall bring together local cancer stakeholders, develop bylaws, identify priority cancer control needs of its region, and develop solutions to solve problems, consistent with the plan and the goal of reducing the burden of cancer in this state. Each collaborative shall meet at least semiannually and send representation to the council meetings.
- (d) By October 15 of each year, the collaborative program shall submit an annual report to the council. The council shall have input into the prioritization of programs and proposed allocation of resources in the program consistent with the plan.
  - (e) The Cancer Control Collaborative Program shall serve as

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the infrastructure for expansion or adaptation as federal programs or other opportunities arise for future cancer control initiatives. The development of the infrastructure for local cancer control collaboratives, to the extent possible, shall be designed to leverage opportunities for funding from the United States Centers for Disease Control or other federal sources.

Section 8. Subsection (1) and paragraph (a) of subsection (2) of section 458.324, Florida Statutes, are amended to read:

458.324 Breast cancer; information on treatment alternatives.—

- "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and  $\frac{\text{Resource Research Advisory Council in accordance with } \underline{s.}}{381.923(4)(0)} = \frac{1004.435(4)(m)}{s.}$
- (2) COMMUNICATION OF TREATMENT ALTERNATIVES.—Each physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast cancer shall inform such patient of the medically viable treatment alternatives available to such patient; shall describe such treatment alternatives; and shall explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:
  - (a) The physician may, in his or her discretion:

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1. Orally communicate such information directly to the patient or the patient's legal representative;

- 2. Provide the patient or the patient's legal representative with a copy of the written summary prepared in accordance with  $\underline{s.\ 381.923(4)(o)}\ \underline{s.\ 1004.435(4)(m)}$  and express a willingness to discuss the summary with the patient or the patient's legal representative; or
- 3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.

Nothing in this subsection shall reduce other provisions of law regarding informed consent.

Section 9. Subsection (1) and paragraph (a) of subsection (2) of section 459.0125, Florida Statutes, are amended to read:

459.0125 Breast cancer; information on treatment alternatives.—

- "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and Resource Research Advisory Council in accordance with  $\underline{s}$ . 381.923(4)(o)  $\underline{s}$ . 1004.435(4)(m).
- (2) COMMUNICATION OF TREATMENT ALTERNATIVES.—It is the obligation of every physician treating a patient who is, or in the judgment of the physician is at high risk of being,

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diagnosed as having breast cancer to inform such patient of the medically viable treatment alternatives available to such patient; to describe such treatment alternatives; and to explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:

- (a) The physician may, in her or his discretion:
- 1. Orally communicate such information directly to the patient or the patient's legal representative;
- 2. Provide the patient or the patient's legal representative with a copy of the written summary prepared in accordance with  $\underline{s.\ 381.923(4)(o)}\ \underline{s.\ 1004.435(4)(m)}$  and express her or his willingness to discuss the summary with the patient or the patient's legal representative; or
- 3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.

Nothing in this subsection shall reduce other provisions of law regarding informed consent.

Section 10. <u>Section 1004.435</u>, <u>Florida Statutes</u>, is repealed.

Section 11. This act shall take effect July 1, 2010.