

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 5303 PCB HCA 23-02 Biomedical Research

SPONSOR(S): Health Care Appropriations Subcommittee, Garrison

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Care Appropriations Subcommittee	13 Y, 0 N	Guy-Hudson	Clark
1) Appropriations Committee	26 Y, 0 N	Guy-Hudson	Pridgeon

SUMMARY ANALYSIS

Cancer is the second most common cause of death in the United States, accounting for nearly one of every four deaths and, in Florida, is the second leading cause of death. For over 20 years, the Florida Legislature has created programs and associated funding to build research capacity among research institutions and health systems working towards finding a cure for cancer. To further expand research capacity, the bill adds qualified uses to research funding and expands qualifying entities for funding eligibility.

The bill conforms law to the General Appropriations Act (GAA) proposed by the House of Representatives for Fiscal Year 2023-2024. The bill:

- Expands those cancer centers eligible for funding pursuant to the Casey DeSantis Cancer Research Program (DeSantis program) to include cancer centers designated by the National Cancer Institute as a comprehensive cancer center with at least one geographic site in Florida.
- Exempts \$37,771,257 from the annual allocation fraction calculation for participating cancer centers in the DeSantis program and distributes those funds to participating cancer centers using the proportion as determined by the calculation.
- Eliminates authorization for the endowed research chair contained within the Bankhead-Coley Cancer Research Program.
- Expands eligible programs for funding from the Biomedical Research Trust Fund to include "other cancer research initiatives as appropriated by the Legislature."

The bill provides an effective date of July 1, 2023.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Cancer is the general name for a group of more than 100 diseases. Although there are many kinds of cancer, all cancers start because abnormal cells grow out of control. Untreated cancers can cause serious illness and death. Cancer affects one in three people in the United States.¹

About 1,958,310 new cancer cases are expected to be diagnosed in 2023 in the United States, with approximately 162,410 of those occurring in Florida. In 2023, about 609,820 Americans are expected to die of cancer, almost 1,670 people per day.² Cancer is the second most common cause of death in the United States, exceeded only by heart disease, accounting for nearly one of every four deaths. The National Cancer Institute estimates that approximately 17 million Americans with a history of cancer were alive on June 11, 2019. Some of these individuals were cancer free, while others still had evidence of cancer and may have been undergoing treatment.³

Cancer is the second leading cause of death in Florida.⁴ Florida has the second-highest number of newly-diagnosed cancer cases in the U.S., despite being the fourth-largest state in terms of population. According to the American Cancer Society, breast cancer is the most common cancer for women in the United States.⁵ In 2019, the year for which the most recent statistics are available, breast cancer was the third leading cause of cancer-related death in Florida.⁶

The National Cancer Institute

The National Cancer Institute (NCI) is the federal government's principal agency for cancer research and training.⁷ One function of the NCI is to designate cancer centers by recognizing an institution for the type and breadth of research conducted in addition to the leadership and resources that the cancer center offers. Such designation is nationally recognized as a marker of high-quality cancer care and research. The NCI designates institutions as:⁸

- Comprehensive Cancer Centers – focused on substantial transdisciplinary research that bridges all cancer-related research areas;
- Cancer Centers – focused on one research area such as clinical, prevention, cancer control or population science research; or
- Basic Laboratory Cancer Centers - focused on laboratory research and work collaboratively with other institutions.

¹ American Cancer Society, *What is Cancer*, available at: <http://www.cancer.org/cancer/cancerbasics/what-is-cancer> (last visited March 9, 2023).

² American Cancer Society, *Incidence Drops for Cervical Cancer Drop But Rises for Prostate Cancer*, available at: <https://www.cancer.org/latest-news/facts-and-figures-2023.html#:~:text=Cancer%20continues%20to%20be%20the.about%201%2C670%20deaths%20a%20day> (last visited March 18, 2023).

³ American Cancer Society, *Cancer Facts and Figures 2023*, available at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf> (last visited March 9, 2023).

⁴ Florida Vital Statistics, *Annual Report 2021-Deaths*, available at: <http://www.flpublichealth.com/Vsbook/PDF/2021/VSCOMP.pdf> (last visited March 9, 2023).

⁵ American Cancer Society, *Key Statistics for Breast Cancer*, available at: <https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html#:~:text=Trends%20in%20breast%20cancer%20deaths&text=The%20chance%20that%20a%20woman.decline%20of%2043%25%20through%202020> (last visited March 18, 2023).

⁶ Florida Statewide Cancer Registry, *Florida Cancer Data System, Number of Cancer Deaths by Sex, Race and Age Group, Florida 2019*, available at: [https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2019/Table_No_T15_\(2019\).pdf](https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2019/Table_No_T15_(2019).pdf).

⁷ National Cancer Institute, *National Cancer Institute Overview and Mission*, available at: <https://www.cancer.gov/about-nci/overview> (last visited March 18, 2023).

⁸ National Cancer Institute, *NCI-Designated Cancer Centers*, available at: <https://www.cancer.gov/research/infrastructure/cancer-centers> (last visited March 18, 2023).

Currently there are two NCI-designed comprehensive cancer centers in Florida: Mayo Clinic Cancer Center Jacksonville, Florida, (in addition to facilities in Arizona and Minnesota); and, H. Lee Moffitt Cancer Center. A third, University of Miami Sylvester Comprehensive Cancer Center, is an NCI-designated cancer center.⁹ The University of Florida Shands Cancer Hospital is currently in process of applying for NCI designation.

The Casey DeSantis Cancer Research Program

In 2014, the Legislature created the Florida Consortium of National Cancer Institute Centers Program, renamed the Casey DeSantis Cancer Research Program (DeSantis program) in 2022.¹⁰ Established to: enhance the quality and competitiveness of cancer care in Florida; further a statewide biomedical research strategy directly responsive to the health needs of Florida's citizens; and, capitalize on potential educational opportunities available to students, the program funds Florida-based,¹¹ NCI-designated cancer centers according to a statutory formula.¹²

A participating cancer center's annual allocation is determined by multiplying the funds appropriated for the DeSantis program in the General Appropriations Act by an allocation fraction calculation determined by the Department of Health (DOH).¹³ The DOH must calculate a participating cancer center's allocation fraction on or before September 15 each year using a specific statutory formula.¹⁴ The program sets a floor of funding at \$16 million in cases where a participating cancer center's allocation equals less. The difference is made up using funds proportionally redistributed from other participating cancer centers' allocations.¹⁵

A participating cancer center's allocation fraction calculation is determined by DOH using a tier-weighted formula that factors in a cancer center's reportable cancer cases; peer-review costs; and biomedical education and training.¹⁶ The tier designations that weight DOH's annual allocation calculation are based on the participating cancer center's NCI-designation status. The program's three tier designations are:¹⁷

- Tier 1: Florida-based NCI-designated comprehensive cancer centers;
- Tier 2: Florida-based NCI-designated cancer centers; and
- Tier 3: Florida-based cancer centers seeking NCI-designation as well as meeting additional criteria related to their research and biomedical education.

Currently, three cancer centers participate in the program:

- H. Lee Moffitt Cancer Center, which is an NCI-designated comprehensive cancer center;
- Sylvester Comprehensive Cancer Center at the University of Miami, which is an NCI-designated cancer center; and
- The University of Florida Health Cancer Center, which is pursuing an NCI-designation.

During the 2022 Legislative Session, the Legislature appropriated an additional \$37,771,257 to the DeSantis program, bringing the total appropriation to \$100 million. The funds were required to be excluded from the statutory distribution formula and be distributed in the same proportion as required to be allocated to each participating cancer center under the allocation fraction calculation.¹⁸

Participating cancer centers are required to work with DOH to prepare and submit a report to the

⁹ National Cancer Institute, *NCI-Designated Cancer Centers*, "Find a Cancer Centers" directory, available at: <https://www.cancer.gov/research/infrastructure/cancer-centers/find> (last visited March 18, 2023).

¹⁰ Section 381.915, F.S.

¹¹ "Florida-based" means that a cancer center's actual or sought designated status is or would be recognized by the NCI as primarily located in Florida and not in another state. Section 381.915(3)(c), F.S.

¹² Section 381.915(6), F.S. Distributions pursuant to the DeSantis program are subject to annual appropriation by the Legislature.

¹³ *Id.*

¹⁴ Section 381.915(3), F.S.,

¹⁵ *Supra*, note 12.

¹⁶ Section 381.915(5), F.S.

¹⁷ Section 381.915(4), F.S.

¹⁸ Section 29 of Chapter 2022-157, Laws of Florida.

Cancer Control and Research Advisory Council which includes specific metrics relating to cancer mortality and external funding for cancer-related research in the state. If a participating cancer center does not endorse this report or produce an equivalent independent report, the cancer center shall be suspended from the DeSantis program for one year. Among other elements, the report must include an analysis of specific trending age-adjusted cancer mortality rates in the state for: lung cancer; pancreatic cancer; sarcoma; melanoma; leukemia and myelodysplastic syndromes; and, brain cancer.

Biomedical Research in Florida

The Biomedical Research Trust Fund consists of funds appropriated by the Legislature for the James and Esther King Biomedical Research Program, the Casey DeSantis Cancer Research Program (DeSantis program), and the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley program) as specified in ss. 215.5602, 381.915, and 381.922, F.S., respectively. Currently, \$37.3 million is annually appropriated from the Biomedical Research Trust Fund for these programs.

Created in 2006, the Bankhead-Coley program within the DOH funds research grants for progress towards cures for cancer that attract new talent and increase participation in clinical trials. Emphasis is given to efforts that significantly expand cancer research capacity in the state.¹⁹

One element of the Bankhead-Coley program, endowments to cancer research institutions, are provided to establish a funded research chair that will attract and retain a promising researcher in order to serve as a catalyst to attract other national grant-producing researchers to the state. The endowments are contingent upon funding in the General Appropriations Act (GAA). The purpose of the endowment is to provide secure funding for at least seven years to attract an experienced and promising researcher whose continued employment for this period is not contingent upon grant awards associated with time-limited research projects.²⁰

The research institution that receives an endowed chair must submit an annual report to the Governor, the President of the Senate and Speaker of the House of Representatives describing the research program and the responsibilities of the endowed chair. Upon final selection of the researcher, or if a replacement is needed for the original endowed chair, the research institution must notify the Chairs of the Appropriations Committees of the Senate and House of Representatives of the name of the researcher and specific information about the endowment budget and research responsibilities.²¹

In Fiscal Year 2022-2023, the Legislature appropriated \$6 million from the General Revenue Fund, of which \$1 million is nonrecurring, for the endowed chair in the Bankhead-Coley program.

Florida Cancer Innovation Fund

On February 1, 2023, Governor Ron DeSantis, released the “Framework for Freedom” proposed budget for Fiscal Year 2023-2024 and included the establishment of the Florida Cancer Innovation Fund within the Biomedical Research Trust Fund to support innovative cancer research in the state.

According to the Governor’s proposed budget document:²²

Florida takes a comprehensive approach in implementing cancer control efforts to reduce the disparities, morbidity and mortality associated with this disease.

¹⁹ Section 381.922(2), F.S.

²⁰ Section 381.322(4), F.S.

²¹ *Id.*

²² Governor Ron DeSantis, *Framework for Freedom Budget*, HEALTH > COMMUNITY PUBLIC HEALTH (Program) > COMMUNITY HEALTH PROMOTION > FLORIDA CANCER INNOVATION FUND, available at: [http://frameworkforfreedombudget.com/web%20forms/Budget/BudgetIssueDetail.aspx?p=Cancer%20Innovation&AgencyTitle=HEALTH%20%3E%20COMMUNITY%20PUBLIC%20HEALTH%20\(Program\)%20%3E%20COMMUNITY%20HEALTH%20PROMOTION%20%3E%20&si=64200100&pc=1602000000&icd=6200140&title=FLORIDA%20CANCER%20INNOVATION%20FUND](http://frameworkforfreedombudget.com/web%20forms/Budget/BudgetIssueDetail.aspx?p=Cancer%20Innovation&AgencyTitle=HEALTH%20%3E%20COMMUNITY%20PUBLIC%20HEALTH%20(Program)%20%3E%20COMMUNITY%20HEALTH%20PROMOTION%20%3E%20&si=64200100&pc=1602000000&icd=6200140&title=FLORIDA%20CANCER%20INNOVATION%20FUND) (last visited March 18, 2023).

The efforts in Florida are guided by several collaborations such as The Florida Cancer Plan, The Biomedical Research Advisory Council's Strategic Research and Goals, State Cancer Councils, The Florida Comprehensive Cancer Control Program, and Region Cancer Control Collaborative Strategic Plans. Funding cancer research initiatives is a priority for Florida, with state funding levels reaching a record level of \$149.4 million in Fiscal Year 2022-2023.

Even though Florida has made progress with its efforts, there is room for improvement in multiple areas and for multiple cancer types. The Florida Cancer Innovation Fund will fund grants to support emerging research and trends and promising practices that can be replicated and expanded upon in Florida.

Effect of Proposed Changes

The bill expands the Casey DeSantis Cancer Research Program to include an NCI-designated comprehensive cancer center with at least one geographic site in Florida as an entity that may qualify for funding according to the statutory formula. The bill clarifies that a consortium that has achieved NCI-designation, or is in the process of doing, must be Florida-based to qualify for Tier 3 weight in the calculation for the formula. A consortium must achieve the NCI designation by June 30, 2024, to continue participation in the program. The bill adds breast cancer to the types of cancer included in the mortality rate report produced by participating cancer centers.

The bill excludes from the allocation fraction calculation \$37,771,257 out of the total annual appropriation for the DeSantis program in the GAA. Those funds shall be distributed to participating cancers centers using the proportion as determined by the calculation.

Contained within the Bankhead-Coley program is a separately funded endowed research chair. The bill eliminates authorization for this research chair.

The bill authorizes funding for "other cancer research initiatives as appropriated by the Legislature" within the Biomedical Research Trust Fund.

B. SECTION DIRECTORY:

- Section 1: Amends s. 20.435, F.S., expanding the uses of the Biomedical Research Trust Fund.
- Section 2: Amends s. 381.915, F.S., revising a definition; authorizing a specified amount from the total appropriated funds for the Casey DeSantis Cancer Research Program to be distributed to participating cancer centers; requiring a report for specified statewide cancer statistics to include breast cancer.
- Section 3: Amends s. 381.922, F.S., removing a certain award of an endowment for a specified program.
- Section 4: Providing an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

- 1. Revenues:
None.
- 2. Expenditures:

The Casey DeSantis Cancer Research Program expansion allowing participation from an NCI-designated comprehensive center with at least one geographical site in Florida requires additional funding to ensure current cancer center participants in the DeSantis program are not negatively impacted by including a new cancer center. The estimated cost of including a new cancer center is approximately \$27.5 million.

The additional funding of \$37,771,257 provided during FY 2022-2023 will continue to be excluded from the statutory distribution formula and will be distributed in the same proportion as required to be allocated to each participating cancer center in s. 381.915, Florida Statutes.

The removal of the endowed cancer research chair in the Bankhead-Coley program will result in the elimination of \$5 million in recurring funds. Funds may be used to support expansion of the DeSantis program.

The expansion of eligible programs for funding from the Biomedical Research Trust Fund to include “other cancer research initiatives” will result in additional recurring funds of \$20 million.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

