

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 Committee on Health Policy

BILL: SB 1010

INTRODUCER: Senator Gibson

SUBJECT: Uterine Fibroid Research and Education

DATE: February 1, 2022

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Pre-meeting
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

I. Summary:

SB 1010 requires the Department of Health (DOH) to develop and maintain an electronic database of information related to uterine fibroids. The bill requires health care providers to submit to the DOH information on the diagnosis or treatment of women with uterine fibroids for inclusion in the database. The bill defines health care providers as physicians licensed under ch. 458, F.S., and autonomous advanced practice registered nurses (AAPRNs).

The bill prohibits the database from including personal identifying information. The information collected is confidential and may be used only by DOH employees or agents for the purpose of conducting research on uterine fibroids. The bill requires the DOH, in consultation with the Florida Medical Association (FMA), to develop and disseminate information related to uterine fibroids for the education of health care providers and to conduct a campaign to increase public awareness of uterine fibroids.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

The Department of Health

The Legislature created the DOH to protect and promote the health of all residents and visitors in the state.¹ The DOH is charged with the regulation of health care practitioners for the preservation of the health, safety, and welfare of the public. The Public Health Research Unit is located within the Division of Community Health Promotion within the DOH.²

¹ Section 20.43, F.S.

² *Id.*

Public Health Research

In 1999, the Legislature established the Lawton Chiles Endowment Fund and the Florida Biomedical Research Program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease.³ The Biomedical Research Program, within the division of Public Health Research in the DOH, administers annual funding opportunities for research grant applications, monitors research grants, evaluates progress of research grant project aims, and provides research consultations and technical assistance. Annual reports are submitted to the Florida Legislature on research progress. The goals of the research grants are to find new discoveries leading to the prevention, treatment, and cures for cancer, tobacco-related diseases, and Alzheimer's disease.

This program is also responsible for the DOH Institutional Review Board (IRB) and the Human Research Protection Program, which provides research consultations and technical assistance concerning applications for research reviewed by the IRB. The IRB reviews research projects that involve clients, data, facilities, and staff.

The Biomedical Research Program also provides two educational programs to enrich the DOH's internal research capacity: the Research Excellence Initiative and Florida Health Grand Rounds.

The Research Excellence Initiative is a year-long education program for DOH professionals conducting research, epidemiology, and program evaluation. The initiative builds skills and ability for quality and innovative research with emphasis on research integrity, research ethics, and regulatory requirements. The Research Excellence Initiative is now in its fourth year.⁴

The Florida Health Grand Rounds is a webinar series held in the Fall and Spring semesters in partnership with Florida university-based researchers and hosted by the DOH. The topics have a broad focus, touching on emerging, innovative, and cross-cutting areas of public health. Florida Health Grand Rounds provides an opportunity for Florida researchers to highlight and share their work with DOH staff.⁵

Biomedical Research Program

The Florida Legislature has long recognized the need to support vital research conducted in both academic and private institutions throughout the state through the William G. "Bill" Bankhead Jr. and David Coley Cancer Research Program (Bankhead-Coley Program); the James and Esther King Biomedical Research Program (King Program); and the Live Like Bella Pediatric Cancer Research Initiative (Bella Initiative), the latter of which is funded through the Bankhead-Coley

³ Chapter 99-167, s. 2, Laws of Fla.

⁴ Department of Health, Provider and Partner Resources, Research, *Research Excellence Initiative*, available at <http://www.floridahealth.gov/provider-and-partner-resources/research/academy-of-research-excellence.html> (last visited Jan. 25, 2022).

⁵ Department of Health, Provider and Partner Resources, Research, *Florida Health Grand Rounds*, available at <http://www.floridahealth.gov/provider-and-partner-resources/research/florida-health-grand-rounds/index.html> (last visited Jan. 25, 2022).

Program, is now in its fifth year, and is the only state-funded pediatric cancer research program in the U.S.⁶

Total funding, in the amount of \$18,505,007, was awarded to Bankhead-Coley and King program and Bella Initiative grantees. This funding during fiscal year (FY) 2020-21, resulted in 13 Bankhead-Coley, 12 King, and 11 Bella Initiative new research grants. These awards are made to universities and cancer research centers across the state to support researchers for improving prevention, diagnosis, and treatment.⁷

Research grants are awarded through a competitive peer review process. Awards are based on scientific merit as determined via independent peer review by experts located outside Florida who are free from conflicts of interest. Full-time researchers at any Florida-based university or established research institution are eligible to apply. All researchers provide a legislative report that is used to produce an annual report.⁸

James and Esther King Biomedical Research Program

In 1999 the Legislature enacted s. 215.5602, F.S., which established within the DOH the King Program. The purpose of the 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. The Legislature established the following long-term goals for the King Program:

- Improve Floridians' health by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease;
- Expand biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease;
- Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers;
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional outside the state funding.
- Stimulate economic activity in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.⁹

Funds appropriated by the Legislature for the King Program must be used exclusively for the award of grants and fellowships 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 the King Program's administrative expenses. Priority must be granted to research designed to prevent or cure disease.

⁶ Department of Health, Biomedical Research Advisory Council Report, *William G. "Bill" Bankhead Jr., and David Coley Cancer Research Program, James and Esther King Biomedical Research Program, and Live Like Bella Pediatric Cancer Research Initiative, 2020-2021*, p. 2., available at <http://www.floridahealth.gov/provider-and-partner-resources/research/research-programs1/2021BiomedicalResearchAdvisoryCouncilAnnualReport.pdf> (last visited Jan. 25, 2022).

⁷ *Id.*

⁸ *Supra* note 6.

⁹ Section 215.5602, F.S.

Section 215.5602, F.S., also created within the DOH the Biomedical Research Advisory Council (council). The council advises the Surgeon General as to the direction and scope of the biomedical research programs. All grants and fellowships are awarded by the Surgeon General, in consultation with the council, on the basis of scientific merit, as determined by the competitively open, peer-reviewed process to ensure objectivity, consistency, and high quality. The following types of applications may be considered for funding:

- Investigator-initiated research grants;
- Institutional research grants; and
- Predoctoral and postdoctoral research fellowships.¹⁰

The council awards grants for cancer research through the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922, F.S.¹¹

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

The Legislature established the Bankhead-Coley Program in 2004 with the enactment of s. 381.922, F.S. The Legislature gave the Bankhead-Coley Program two goals to expand cancer research capacity in the state: expand capacity, and improve research and treatment through greater participation in clinical trials.

The Bankhead-Coley Program expands cancer research capacity by:

- Identifying ways to attract new research talent and national grant-producing researchers to cancer research facilities;
- Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research;
- Funding proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
- Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
- Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
- Aiding in other multidisciplinary research-support activities to advance cancer research.¹²

The Bankhead-Coley Program’s second goal is to improve research and treatment through greater participation in clinical trials networks by:

- Identifying ways to increase adult enrollment in cancer clinical trials;
- Supporting public and private professional education programs designed to increase awareness and knowledge about cancer clinical trials;
- Providing tools to cancer patients and community-based oncologists to aid in the identification of available cancer clinical trials available;

¹⁰ *Id.*

¹¹ Section 215.5602(11), F.S.

¹² Section 381.922, F.S.

- Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks; and
- Reducing 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.¹³

Live Like Bella Pediatric Cancer Research Initiative

Within the Bankhead -Coley Program, the Legislature also established the Bella Initiative. The purpose of the Bella Initiative is to advance progress toward curing pediatric cancer by awarding grants through a peer-reviewed, competitive process.

The DOH also administers funding opportunities for the Bella Initiative which is subject to annual appropriation of funds by the Legislature.¹⁴ The Bella Initiative pursues the following goals:

- Significantly expand pediatric cancer research capacity in Florida;
- Improve both research and treatment through greater pediatric enrollment in clinical trials networks; and
- Reduce the impact of pediatric cancer on disparate groups.¹⁵

Ed and Ethel Moore Alzheimer's Disease Research Program

In 2014, the Legislature created the Ed and Ethel Moore Alzheimer's Disease Research Program (Moore Alzheimer's Program) within the DOH to fund research leading to prevention of or a cure for Alzheimer's disease. The Legislature established the program's long-term goals to improve Floridians health, expand the foundation of knowledge relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease, and to stimulate economic activity in the state in areas related to Alzheimer's disease research.¹⁶

The Alzheimer's Disease Research Grant Advisory Board advises the Surgeon General as to the direction and scope of the Alzheimer's disease research program. Grants and fellowships must be awarded by the Surgeon General, after consultation with the board, on the basis of scientific merit.¹⁷

Uterine Fibroids

Uterine fibroid lesions were initially known as the "uterine stone." The term "fibroid" was first introduced in the 1860s. Uterine fibroids are the most common pelvic tumors among women of

¹³ Department of Health, Provider and Partner Resources Research, Research Programs, Research on Cancer and Tobacco-related Diseases, *James and Esther King Biomedical Research Program*, available at <http://www.floridahealth.gov/provider-and-partner-resources/research/research-programs1/research-cancer-tobacco.html> (last visited Jan. 25, 2022).

¹⁴ Section 381.922(2)(c), F.S.

¹⁵ Florida Department of Health, Live Like Bella Pediatric Cancer Research Initiative, Funding Opportunity Announcement, FY 2017 - 2018, Overview, *Introduction*, available at <https://www.floridahealth.gov/provider-and-partner-resources/research/FINAL%20Live%20Like%20Bella%20Pediatric%20Cancer%20Research%20Initiative%20FOA.pdf> (last visited Jan. 25, 2022).

¹⁶ Section 381.82, F.S.

¹⁷ *Id.*

reproductive age, affecting more than 70 percent of women worldwide, particularly women of color.

Although benign, uterine fibroids are associated with significant morbidity; they are the primary indication for hysterectomy and a major source of gynecologic and reproductive dysfunction, ranging from menorrhagia¹⁸ and pelvic pain to infertility, recurrent miscarriage, and preterm labor. The annual U.S. health care costs associated with uterine fibroids have been estimated at approximately \$34 billion. Uterine fibroids thus represent significant societal health and financial burdens on the U.S. health care system and economy.¹⁹

Diagnosis and Treatment

The growth of fibroids that originate from the uterine's smooth muscle tissue (myometrium) is dependent on estrogen and progesterone. Fibroids are rare before puberty, increase in prevalence during the reproductive years, and decrease in size after menopause. Uterine fibroids are classified based on location: subserosal (projecting outside the uterus), intramural (within the myometrium), and submucosal (projecting into the uterine cavity).

The symptoms and treatment options for fibroids are affected by size, number, and location. The most common symptom is abnormal uterine bleeding, usually manifesting as excessive menstrual bleeding. Other symptoms include pelvic pressure, bowel dysfunction, urinary frequency and urgency, urinary retention, low back pain, constipation, and painful intercourse.

Treatment of uterine fibroids should be tailored to the size and location of the tumors; the patient's age, symptoms, desire to maintain fertility, and access to treatment; and the physician's experience. The ideal treatment satisfies four goals: relief of signs and symptoms, sustained reduction of the size of fibroids, maintenance of fertility (if desired), and avoidance of harm.²⁰

Florida Medical Association

Founded in 1874, the FMA is a professional association dedicated to the service and assistance of doctors of medicine and doctors of osteopathic medicine in Florida. The FMA represents more than 25,000 members on issues of legislation and regulatory affairs, medical economics and education, public health, and ethical and legal issues. According to the FMA, the association advocates for physicians and their patients to promote the public health, ensure the highest standards of medical practice, and to enhance the quality and availability of health care in the Sunshine State.²¹

¹⁸ Menorrhagia is heavy or prolonged menstrual bleeding. John Hopkins Medicine, Health, Menorrhagia, *What is menorrhagia?* available at <https://www.hopkinsmedicine.org/health/conditions-and-diseases/menorrhagia> (last visited Jan 27, 2022).

¹⁹ Yang Q, Ciebiera M, Bariani M, Ali M, Elkafas H, Boyer T, and Al-Hendy A, Endocrine Society Oxford, *Endocrine Reviews*, 2022, Vol. XX, No. XX, 1–43 *Comprehensive Review of Uterine Fibroids: Developmental Origin, Pathogenesis, and Treatment*, (Nov. 2021) available at <https://academic.oup.com/edrv/advance-article/doi/10.1210/endrev/bnab039/6422392> (last visited Jan. 27, 2022).

²⁰ Maria Syl D. De La Cruz, MD, & Edward M. Buchanan, MD, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, Pa., published by American Family Physician, Vol. 95, No.2, (Jan. 15, 2017) *Uterine Fibroids: Diagnosis and Treatment*, available at <https://www.aafp.org/afp/2017/0115/afp20170115p100.pdf> (last visited Jan. 27, 2022).

²¹ E-mail from the Florida Medical Association to the Senate Health Policy Committee, (Jan. 27, 2022) (on file with the Senate Health Policy Committee).

III. Effect of Proposed Changes:

SB 1010 creates s. 381.9312, F.S., which requires the DOH to develop and maintain an electronic database of information related to uterine fibroids. The purpose of the database is to encourage research relating to the diagnosis and treatment of uterine fibroids and ensure that women are provided with the relevant information and health care necessary to prevent and treat uterine fibroids.

The bill defines “health care provider” to include a physician licensed under ch. 458, F.S., or an AAPRN registered under s. 464.0123, F. S.; and a “uterine fibroid” as a noncancerous growth of the uterus that often appears during a woman’s childbearing years.

The database must include, but need not be limited to, all of the following information:

- Incidence and prevalence of women diagnosed with uterine fibroids in Florida;
- Demographic attributes of women diagnosed with uterine fibroids in Florida; and
- Treatments and procedures for uterine fibroids used by health care providers in Florida.

A health care provider who diagnoses or treats a woman with uterine fibroids must submit information relating to such diagnosis or treatment to the DOH in a form and manner prescribed by DOH rule for inclusion in the database. Such information may be submitted along with any reports or other information that the health care provider is required to submit to the DOH pursuant to state law.

The database may not include any personal identifying information of women diagnosed with or treated for uterine fibroids. Such information is confidential and may be used only by employees or agents of the DOH for the purpose of conducting uterine fibroid research.

The DOH, in consultation with the FMA, must develop and disseminate information related to uterine fibroids to educate health care providers and conduct a campaign to increase public awareness of uterine fibroids which must include, but need not be limited to, all of the following:

- The possible risk factors for developing uterine fibroids, including, but not limited to, the races or ethnicities of women who have a statistically elevated risk of developing uterine fibroids; and
- The range of available treatment options for uterine fibroids, including, but not limited to, treatments and procedures that are considered alternatives to hysterectomy.

The bill provides an effective date of July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may have an impact on private health care practitioners due to the potential need for additional staff time, record keeping, and reporting of required information on patients with uterine fibroids they diagnose and treat.

C. Government Sector Impact:

The DOH estimates a fiscal impact of \$1,426,688, including \$1,210,149 in nonrecurring funds and \$216,539 in recurring funding, to procure, develop, and implement the required database, as well as training health care providers on the bill's new reporting requirement. This funding includes three data-entry staff and one epidemiologist in the "other personal services" category.²²

VI. Technical Deficiencies:

None.

VII. Related Issues:

"Health care provider" is defined to include a physician licensed under ch. 458, F.S., or an AAPRN registered under s. 464.0123, F.S., but does not include osteopathic physicians licensed under ch. 459, F.S., who also diagnose and treat uterine fibroids.

VIII. Statutes Affected:

This bill creates section 381.9212 of the Florida Statutes.

²² E-mail from the Department of Health to the Senate Health Policy Committee (Jan. 24, 2022) (on file with Senate Health Policy Committee).

IX. Additional Information:

- A. **Committee Substitute – Statement of 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.
