

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 Appropriations

BILL: CS/SB 1010

INTRODUCER: Health Policy Committee and Senator Gibson

SUBJECT: Uterine Fibroid Research and Education

DATE: February 25, 2022

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	Howard	Money	AHS	Recommend: Favorable
3.	Howard	Sadberry	AP	Pre-meeting

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1010 requires the Department of Health (department) to develop and maintain an electronic database of information related to uterine fibroids. The bill requires specified health care providers to submit to the department 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 chapters 458 or 459, Florida Statutes, and autonomous advanced practice registered nurses (AAPRNs) licensed under section 464.0123, Florida Statutes.

The bill prohibits the database from including personal identifying information. The information collected is confidential and may be used only by the department employees or agents for the purpose of conducting research on uterine fibroids. The bill requires the department to develop and include information related to uterine fibroids in literature on women's health care which is currently made available to the public, to increase public awareness of uterine fibroids. The information must include possible risk factors for developing uterine fibroids and the range of available treatment options that are considered alternatives to a hysterectomy.

The department estimates a fiscal impact of \$1.4 million to procure, develop, and implement the required database, as well as training health care providers on the bill's new reporting requirement. See section V of this analysis.

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

II. Present Situation:

The Department of Health

The Legislature created the department to protect and promote the health of all residents and visitors in the state.¹ The department 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 department.²

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 department, 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 department 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 department's internal research capacity: the Research Excellence Initiative and Florida Health Grand Rounds.

The Research Excellence Initiative is a year-long education program for the department 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 department. The topics have a broad focus, touching on emerging, innovative, and cross-cutting areas of public health.

¹ Section 20.43, F.S.

² *Id.*

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).

Florida Health Grand Rounds provides an opportunity for Florida researchers to highlight and share their work with the department 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 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 2020-2021, 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

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 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 menorrhagia⁹ and pelvic pain to infertility, recurrent miscarriage, and preterm

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).

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 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).

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.¹⁰

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.¹¹

III. Effect of Proposed Changes:

The bill creates s. 381.9312, F.S., which requires the department 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 physicians licensed under chs. 458 or 459, F.S., or an A APRN 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.

¹⁰ 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/edrv/bnab039/6422392> (last visited Jan. 27, 2022).

¹¹ 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).

A health care provider who diagnoses or treats a woman with uterine fibroids must submit information relating to such diagnosis or treatment to the department in a form and manner prescribed by the department 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 department 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 department for the purpose of conducting uterine fibroid research.

The department must develop and include information related to uterine fibroids in literature on women's health care which is currently made available to the public, to increase public awareness of uterine fibroids. The information must include, but need not be limited to:

- The possible risk factors of developing uterine fibroids; and
- The range of available treatment options that are considered alternatives to a 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:

CS/SB 1010 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 Department of Health (department) 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.¹²

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 381.9312 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 2, 2022:

The CS:

- Revises the bill's definition of "health care provider" to include allopathic and osteopathic physicians, as opposed to only allopathic physicians as in the underlying bill;
- Clarifies that AAPRNs referenced in the definition are autonomous AAPRNs;
- Deletes the FMA's participation in the department's development and dissemination of information to health care providers and in the bill's public awareness campaign; and
- Revises the risk factors for which the department must develop information related to fibroids in women's health care.

B. Amendments:

None.

¹² E-mail from the Department of Health to the Senate Health Policy Committee (Jan. 24, 2022) (on file with Senate Health Policy Committee).

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