

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/CS/HB 543 Uterine Fibroid Research and Education

SPONSOR(S): Health & Human Services Committee, Appropriations Committee, Professions & Public Health Subcommittee, Omphroy and others

TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1010

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	15 Y, 0 N, As CS	Rahming	McElroy
2) Appropriations Committee	20 Y, 0 N, As CS	Aderibigbe	Pridgeon
3) Health & Human Services Committee	16 Y, 0 N, As CS	Rahming	Calamas

SUMMARY ANALYSIS

Uterine fibroids are tumors that grow in a woman's uterus and are the most common benign tumors affecting women. They are rare before puberty, increase in prevalence during the reproductive years, and decrease in size after menopause. Treatment of fibroids depends on a woman's age, general health, symptoms, type of fibroids, whether she is pregnant, and her desire to have children in the future. Treatment ranges from minimally invasive hormonal and medical treatments to major surgical interventions, such as hysterectomy.

Under current law, the Florida Department of Health (DOH) is not required to provide women information on fibroids. Additionally, providers who treat women with fibroids are not required to submit information relating to such diagnoses and treatments to DOH, and DOH does not have a centralized database to track this data.

CS/CS/CS/HB 543 requires physicians, physician assistants, and advanced practice registered nurses who diagnose and treat women with fibroids to submit information relating to such diagnosis or treatment to DOH. It requires DOH to develop and maintain an electronic database of information related to uterine fibroids that includes, at a minimum, the following information:

- Incidence and prevalence of women diagnosed with fibroids in Florida;
- Demographic attributes of women diagnosed with fibroids in Florida; and
- Treatments and procedures for fibroids used by physicians and physician assistants licensed under chapters 458 and 459, F.S., and APRNs licensed under ch. 464, F.S.

The bill prohibits DOH from including any personal identifying information of women with fibroids in its database.

The bill also requires DOH to develop and include specified information about fibroids in certain women's health care educational materials, including alternative treatment options to hysterectomy.

The bill provides an appropriation of \$681,048 in nonrecurring funds and \$121,852 in recurring funds from the General Revenue Fund to DOH to implement the provisions of the bill.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Uterine Fibroids

Uterine fibroids, which are tumors that grow in a woman's uterus,¹ place significant financial burdens on the U.S. health care system and economy, with an estimated \$34 billion in associated annual health care costs.² These growths are typically benign (noncancerous) and are the most common benign tumor affecting women.³ They are rare before puberty, increase in prevalence during the reproductive years, and decrease in size after menopause. As many as one in five women have fibroids during their childbearing years and half of all women have them by age 50. Fibroids are also more common in Black than White, Hispanic, or Asian women.⁴

Although the exact cause of fibroids is unknown, they are thought to be caused by hormones in the body and family history or genes.⁵ In addition to age, race and ethnic origin, and family history, other known risk factors include:⁶

- Obesity
 - Overweight or obese women are two or three times more likely to get fibroids than normal weight women.
- Eating Habits
 - Eating a lot of red meat and ham is linked with higher risk of fibroids.
- Vitamin D deficiency
 - Vitamin D inhibits fibroid growth, but studies indicate only 10 percent of Black women have adequate levels.⁷

Diagnosis of Fibroids

Fibroids vary in size and weight⁸ and can grow in different parts of the uterus.⁹ Although it is possible for just one fibroid to develop, most often there are multiple. Fibroids are not always easy to diagnose, as some women have no symptoms. However, common symptoms are bleeding between periods, heavy bleeding during periods, periods that last longer than normal, urinary frequency and urgency, pelvic cramping or pain with periods, feeling fullness or pressure in the lower belly, and painful intercourse.¹⁰

¹ The uterus is a hollow muscular organ that nourishes the developing baby during pregnancy. University of Florida Health (UFHealth), *Hysterectomy*, <https://ufhealth.org/hysterectomy> (last visited Feb. 8, 2022).

² 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).

³ National Center for Biotechnology Information (NCBI), *Uterine Leiomyomata*, <https://www.ncbi.nlm.nih.gov/books/NBK546680/> (last visited Feb. 7, 2022).

⁴ UFHealth, *Uterine Fibroids*, <https://ufhealth.org/uterine-fibroids> (last visited Feb. 7, 2022).

⁵ *Id.*

⁶ Florida Department of Health (DOH) Hernando County, *Uterine Fibroids in Florida, 2021 Narrative Summary of the Data*, <https://hernando.floridahealth.gov/newsroom/2021/07/UterineFibroids2021Report.html> (last visited Feb. 7, 2022).

⁷ *Id.* Sunlight in moderation, supplements, and certain food sources can help improve Vitamin D levels.

⁸ *Supra* note 4. Some fibroids are microscopic, while others fill the entire uterus and weigh several pounds.

⁹ *Supra* note 4. Fibroids can grow in the muscle wall of the uterus (myometrial); just under the surface of the uterine lining (submucosal); just under the outside lining of the uterus (subserosal); or on a long stalk on the outside the uterus or inside the uterus (pedunculated).

¹⁰ *Supra* note 4.

Fibroids can also be diagnosed through a pelvic exam, which may show a change in the shape of a woman's uterus, or through the following tests:¹¹

- Ultrasound, which uses sound waves to create a picture of the uterus.
- MRI, which uses powerful magnets and radio waves to create a picture.
- Saline infusion sonogram, where saline is injected into the uterus to make it easier to see the uterus using ultrasound.
- Hysteroscopy, which uses a long, thin tube inserted through the vagina and into the uterus to examine the inside of the uterus.
- Endometrial biopsy, which removes a small piece of the lining of the uterus to check for cancer if a woman has unusual bleeding.

Treatment of Fibroids

Treatment of fibroids depends on a woman's age, general health, symptoms, type of fibroids, whether she is pregnant, and her desire to have children in the future. Treatment ranges from minimally invasive hormonal and medical treatments to major surgical interventions, such as hysterectomy.

Non-Surgical Treatment

There are various treatments for the symptoms of fibroids, such as intrauterine devices (IUDs) that release hormones to help reduce heavy bleeding and pain and tranexamic acid to reduce the amount of blood flow.¹² There are also medical or hormonal therapies to shrink fibroids,¹³ including a type of IUD that releases a low dose of the hormone progestin into the uterus each day.¹⁴ Medical procedures used to directly treat fibroids include:¹⁵

- Endometrial ablation, a procedure used to treat heavy bleeding associated with fibroids; and
- Uterine artery embolization, a procedure that stops the blood supply to the fibroid, causing it to shrink and die.

Surgical Treatments

Surgical procedures used to treat fibroids include:¹⁶

- Myoscopy, a procedure that removes fibroids growing inside the uterus;
- Myomectomy, a procedure that removes fibroids from the uterus, but does not prevent new fibroids from growing; and
- Hysterectomy

Hysterectomy is a major surgery to remove all or part of a woman's uterus. The fallopian tubes and ovaries may also be removed during the surgery.¹⁷ Hysterectomy is the second most frequently performed surgical procedure, after cesarean section, for women of reproductive

¹¹ *Id.*

¹² Other examples include iron supplements to prevent or treat anemia due to heavy periods; and pain relievers, such as ibuprofen or naproxen, for cramps or pain.

¹³ Other examples include birth control pills to help control heavy periods and hormone shots to help shrink fibroids by stopping ovulation.

¹⁴ *Supra* note 4.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ UFHealth, *Hysterectomy*, <https://ufhealth.org/hysterectomy> (last visited Feb. 8, 2022).

age in the United States. Approximately 600,000 hysterectomies are performed annually in the United States, and approximately 20 million U.S. women have had a hysterectomy.¹⁸

In addition to the general risks of surgery,¹⁹ hysterectomy specific risks include:²⁰

- Injury to the bladder or ureters;
- Pain during sexual intercourse;
- Early menopause if the ovaries are removed;
- Decreased interest in sex; and
- Increased risk of heart disease if the ovaries are removed before menopause.

Florida Department of Health

Licensure of Health Care Providers

Chapter 458, F.S., governs licensure and regulation of allopathic physicians (medical doctors) and physician assistants by the Florida Board of Medicine, in conjunction with the Florida Department of Health (DOH). Chapter 459, F.S., governs licensure and regulation of osteopathic physicians and physician assistants by the Florida Board of Osteopathic Medicine, in conjunction with DOH. Chapter 464, F.S., governs licensure and regulation of advanced practice registered nurses (APRNs) by the Board of Nursing, in conjunction with DOH. These chapters govern licensure qualifications, scope of practice, disciplinary actions, and obligations for such providers.

Uterine Fibroid Reporting and Database

Currently, DOH is not required to provide women information on fibroids and does not have a centralized database to track information for women with fibroids. Additionally, health care providers who diagnose or treat woman with fibroids are not required to submit information relating to such diagnoses or treatments to DOH.

However, DOH does have a data-sharing agreement with the Agency for Health Care Administration (AHCA) related to hospitalizations for fibroids. If a woman has a hospitalization related to fibroids, this information is captured via the hospital discharge record. Current law requires hospitals to submit hospital discharge data to AHCA,²¹ which the AHCA then transmits to DOH per the data-sharing agreement.

Between 2016-2019, there were 16,842 hospitalizations related to fibroids among Florida women ages 15-54 years.²²

Patient Information Privacy

Health Information Portability and Accountability Act (HIPAA)

¹⁸ Centers for Disease Control, *Hysterectomy Surveillance --- United States, 1994—1999*,

<https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5105a1.htm#:~:text=Problem%2FCondition%3A%20Hysterectomy%20is%20the,women%20have%20had%20a%20hysterectomy>. (last visited Feb. 8, 2022).

¹⁹ Risks include blood clots, which may cause death if they travel to the lungs, allergic reactions to medicines, breathing problems, bleeding, infection, and injury to nearby body areas.

²⁰ *Supra*, note 17.

²¹ Health care facilities must submit patient admission and discharge data to AHCA. See s. 408.061, F.S., and R. 59E-7 F.A.C.

²²DOH, Agency Bill Analysis for HB 543, p. 2 (Jan. 27, 2022).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002.²³ These rules address the use and disclosure of an individual's personal health information as well as create standards for information security. Only certain entities are subject to HIPAA's provisions. These "covered entities" include:²⁴

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.

Covered entities are obligated to meet HIPAA's requirements to ensure privacy and confidentiality personal health information, regardless of the method in which the medical service is delivered.

The DOH is a covered entity and the fact that a person is diagnosed or treated for fibroids is PHI.

Personally Identifiable Information

Personally Identifiable Information (PII) is a general term that is used to describe any form of sensitive data that could be used to identify or contact an individual. This term is not related to HIPAA and is not regulated by any one entity or in any one industry like PHI is.²⁵

Effect of the Bill

Uterine Fibroid Reporting and Database

CS/CS/CS/HB 543 requires DOH to develop and maintain an electronic database of information related to uterine fibroids that includes, but is not limited to, the following information:

- Incidence and prevalence of women diagnosed with fibroids in Florida;
- Demographic attributes of women diagnosed with fibroids in Florida; and
- Treatments and procedures for fibroids used in the state.

The bill requires physicians and physician assistants licensed under chapters 458 and 459, F.S., and APRNs licensed under ch. 464, F.S., to submit to DOH information relating to their diagnoses and treatments of women with fibroids, for inclusion in the database. The bill authorizes this information to be submitted with other information the provider must submit to DOH,²⁶ likely increasing efficiencies in reporting required information.

²³ U.S. Department of Health and Human Services (HHS), *The HIPAA Privacy Rule*, available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/> (last visited on Feb. 25, 2022).

²⁴ 45 CFR § 160.103

²⁵ Accountable, *Protected Health Information vs Personal Identifiable Information*, <https://www.accountablehq.com/post/pii-vs-phi#:~:text=Personally%20Identifiable%20Information%2C%20or%20PII%2C%20is%20a%20general%20term%20that,one%20industry%20like%20PHI%20is.> (last visited Feb. 24, 2022). PII has historically been known to just include social security numbers, phone numbers, mailing or email addresses. However, as technology and software have advanced, the breadth of PII has also expanded. PII can also include login IDs, digital images, IP addresses, social media posts and other digital forms of data.

²⁶ Examples include information to be included in the Florida Cancer Data System, pursuant to s. 385.202, F.S., and reports on diseases and conditions pertaining to Epidemiological Research under s. 381.0031, F.S.

The bill also requires DOH to develop and include specified information about fibroids in certain women's health care educational materials, including alternative treatment options to hysterectomy. This increase in awareness may lead more women accepting alternative treatment options to hysterectomy, which may reduce the significant annual health care costs currently associated with hysterectomies.

Patient Information Privacy

The bill prohibits DOH from including any personal identifying information of women diagnosed with or treated for uterine fibroids in the uterine fibroid database.

As a covered entity, DOH is also prohibited under federal law from including this information in the database.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 381.9312, F.S., relating to uterine fibroid research database; education and public awareness.

Section 2: Provides an appropriation.

Section 3: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill provides an appropriation of \$802,900, including \$681,048 in nonrecurring funds and \$121,852 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.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care providers may experience an increase in workload and costs associated with record keeping and the bill's reporting requirement.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 22, 2022, the Appropriations Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Appropriates \$681,048 in nonrecurring funds and \$121,852 in recurring General Revenue to DOH to procure, develop, and implement the required database, as well as train health care providers on the bill's new reporting requirement.

This analysis is drafted to the committee substitute as passed by the Appropriations Committee.

On February 28, 2022, the Health & Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Adds physician assistants to the definition of health care provider.
- Prohibits DOH from including any personal identifying information of women diagnosed with or treated for uterine fibroids in the uterine fibroid database.

This analysis is drafted to the committee substitute as passed by the Health & Human Services Committee.