HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 543 Uterine Fibroid Research and Education
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Rahming	McElroy

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.

The Florida Department of Health (DOH) has programs that provide education on the importance of women's health and well-woman care, and offers follow-up and referral services based on an individual's history and need for medical or social services. However, under current law, DOH is not required to provide women information on fibroids. Additionally, DOH does not have a centralized database to track the diagnosis and treatment of women with fibroids.

Currently, health care providers who diagnose or treat woman with fibroids, such as allopathic and osteopathic physicians licensed under chapters 458 and 459, F.S., respectively, and autonomous advanced practice registered nurses (AAPRNs) registered under s. 464.0123, F.S., are not required to submit information relating to such diagnoses or treatments to DOH.

PCS for HB 543 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 specified health care providers in Florida.

The bill requires allopathic and osteopathic physicians and AAPRNs who diagnose or treat a woman with fibroids to submit information relating to such diagnosis or treatment to DOH.

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 has a significant, negative fiscal impact on DOH and no fiscal impact on local governments.

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 only 10 percent of Black women had adequate levels.[7]

Diagnosis of Fibroids

Fibroids vary in size and weight[8] 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]

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[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/endrev/bnab039/6422392 (last visited Jan. 27, 2022).
[3] National Center for Biotechnology Information (NCBI), *Uterine Leiomymomata*, 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]

- Mysteroscopy, 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.

Public Health Programs for Women's Health

The DOH, in conjunction with the Florida Agency for Health Care Administration (AHCA), has implemented the Family Planning Medicaid Waiver Program,[21] which provides education on the importance of women's health and well-woman care. The program also offers pregnancy testing and counseling, physical examinations, screening for hypertension, breast and cervical cancer, and sexually transmitted diseases, including HIV counseling and testing. Follow-up and referral services are based on an individual's history and need for medical or social services, including referrals for additional services for women diagnosed with having fibroids.[22]

A woman is eligible for the program if she:[23]

- Is between the ages of 14 and 55;
- Has lost full Medicaid services for any reason in the past 24 months;
- Wants to have family planning services;
- Is not pregnant;
- Has not had a hysterectomy or sterilization (tubes tied); and
- Has a household income less than or equal to 185% of the federal poverty level.[24]

Uterine Fibroid Reporting and Database

Currently, DOH does not provide women information on fibroids and does not have a centralized database to track information for women with fibroids. DOH does however, have a data-sharing agreement with AHCA related to hospitalizations for fibroids. If a woman has a hospitalization related to fibroids, this information is captured via the hospital discharge record.[25] AHCA receives this information and transmits it 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.[26]

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[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] The program is also known as Family Planning Medicaid for Today's Woman.
[22] DOH, Women's Health, https://www.floridahealth.gov/%5C/programs-and-services/womens-health/index.html (last visited Feb. 9, 2022).
[23] *Id*.
[24] For 2021, 185% of the FPL for a family of four is $49,025 annually (or $4,085 per month). *See*, *Poverty Guideline, 48 Contiguous States (all states except AK and HI)*, https://aspe.hhs.gov/sites/default/files/private/aspe-files/107166/2021-percentage-poverty-tool_0.pdf (last visited Feb. 9, 2022).
[25] R. 59E-7 F.A.C.
[26] DOH, Agency Bill Analysis for HB 543, p. 2 (Jan. 27, 2022).

Currently, health care providers who diagnose or treat woman with fibroids, such as allopathic and osteopathic physicians licensed under chapters 458 and 459, F.S., respectively, and autonomous advanced practice registered nurses (AAPRNs) registered under s. 464.0123, F.S., are not required to submit information relating to such diagnoses or treatments to DOH.

Effect of the Bill

PCS for 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 by medical doctors and osteopathic physicians licensed under chapters 458 or 459, F.S., and autonomous APRNs registered under s. 464.0123, F.S.

The bill requires allopathic and osteopathic physicians and AAPRNs who diagnose or treat a woman with fibroids, to submit such information relating to such diagnosis or treatment to DOH for inclusion in the database. The bill authorizes this information to be submitted with other information the provider must submit to DOH, likely increasing efficiencies in reporting required information.

The bill 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 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 effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:[27]

   Year 1: DOH estimates a fiscal impact of $803,092, including $681,048 in nonrecurring funds and $122,044 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.

   Year 2+: DOH estimates a fiscal impact of $392,044 in recurring funding for oversight of the database and database server maintenance and upgrades.

[27] DOH, Agency Bill Analysis for HB 543, p. 4 (Jan. 27, 2022).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners 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