

116TH CONGRESS
2D SESSION

S. 4397

To provide for research and education with respect to uterine fibroids, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2020

Ms. HARRIS (for herself, Mr. VAN HOLLEN, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for research and education with respect to uterine fibroids, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Uterine Fibroid Re-
5 search and Education Act of 2020”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) It is estimated that between 20 and 30 per-
9 cent of women of reproductive age have clinically
10 recognized uterine fibroids, and screening studies in-

1 dicate the prevalence of uterine fibroids in women
2 may be much higher.

3 (2) In the United States, an estimated
4 26,000,000 women between the ages of 15 and 50
5 have uterine fibroids. Uterine fibroids may cause sig-
6 nificant morbidity through their presence in the
7 uterus and pelvic cavity, causing significant pelvic
8 pain, iron-deficiency anemia, miscarriages, infer-
9 tility, and heavy bleeding—one of the most common
10 and bothersome symptoms.

11 (3) The pain, discomfort, stress, and other
12 physical and emotional symptoms of living with
13 fibroids may significantly interfere with a woman’s
14 quality of life, compromising her ability to function
15 normally or work or care for her family, and may
16 lead to more severe health and wellness issues.

17 (4) The development of uterine fibroids is a
18 common and significant health problem, affecting
19 women, primarily of reproductive age, across all
20 ages, racial backgrounds, and socioeconomic levels.

21 (5) Most women will experience uterine fibroids
22 by the age of 50, yet few data exist describing the
23 overall patient experience with fibroids. Women with
24 fibroids or symptoms suggestive of fibroids experi-
25 ence significant distress that reduces quality of life

1 and many women are likely undiagnosed, under-
2 scoring the need for improved awareness and edu-
3 cation.

4 (6) Minority women are more likely to develop
5 uterine fibroids. It is estimated that more than 80
6 percent of African-American women and about 70
7 percent of Caucasian women develop fibroids by the
8 time they reach menopause. African-American
9 women have also been shown to have more severe
10 symptoms and develop early-onset uterine fibroids
11 that develop into larger tumors.

12 (7) The exact number of affected women is un-
13 known, because only one out of 4 women who have
14 a uterine fibroid tumor exhibit symptoms severe
15 enough to require treatment.

16 (8) Current research and available data do not
17 provide adequate information on the rates of preva-
18 lence and incidence of fibroids in Asian, Hispanic,
19 and African-American minority women. There is no
20 quantitative data available in regard to the costs as-
21 sociated with treating fibroids, and the methods by
22 which fibroids may be prevented in these women
23 available.

24 (9) Symptomatic uterine fibroids can cause
25 heavy menstrual bleeding, pain, and reproductive

1 problems, including infertility. Women with uterine
2 fibroids are much more likely to miscarry during
3 early pregnancy than women without them.

4 (10) According to the Evidence Report Sum-
5 mary on the Management of Uterine Fibroids, as
6 compiled by the Agency for Healthcare Research and
7 Quality of the Department of Health and Human
8 Services, there is a “remarkable lack of high-quality
9 evidence supporting the effectiveness of most inter-
10 ventions for symptomatic fibroids”.

11 (11) The presence of symptomatic uterine
12 fibroids is the most common reason for hysterecto-
13 mies, accounting for approximately one-third of
14 hysterectomies, or 200,000 procedures annually.
15 Twenty-two percent of African-American women and
16 7 percent of Caucasian women have hysterectomies
17 as a result of uterine fibroids. Lack of patient and
18 provider awareness of less invasive alternatives to
19 hysterectomies lead to an estimated 80,000 to
20 120,000 unnecessary hysterectomies annually. Uter-
21 ine fibroids are also the leading cause of hospitaliza-
22 tion related to a gynecological disorder.

23 (12) The personal and societal costs of uterine
24 fibroids in the United States are significant. Uterine
25 fibroid tumors have been estimated to cost the

1 United States \$5,900,000,000 to \$34,400,000,000
2 annually. The annual direct costs, including surgery,
3 hospital admissions, outpatient visits, and medica-
4 tions, were estimated at \$4,100,000,000 to
5 \$9,400,000,000 annually. Estimated lost work-hour
6 costs ranged from \$1,550,000,000 to
7 \$17,200,000,000 annually. Obstetric outcomes that
8 were attributed to fibroid tumors resulted in costs of
9 \$238,000,000 to \$7,760,000,000 annually.

10 **SEC. 3. RESEARCH WITH RESPECT TO UTERINE FIBROIDS.**

11 (a) RESEARCH.—The Director of the National Insti-
12 tutes of Health (in this section referred to as the “Direc-
13 tor of NIH”) shall expand, intensify, and coordinate pro-
14 grams for the conduct and support of research with re-
15 spect to uterine fibroids.

16 (b) ADMINISTRATION AND COORDINATION.—The Di-
17 rector of NIH, acting through Director of the Office of
18 Research on Women’s Health, shall carry out research
19 conducted pursuant to subsection (a), in coordination with
20 the appropriate institutes, offices, and centers of the Na-
21 tional Institutes of Health, including the National Insti-
22 tute of Child Health and Human Development, the Na-
23 tional Institute of Environmental Health Sciences, the Of-
24 fice of Women’s Health, the Office of Minority Health,
25 and the National Center on Minority Health and Health

1 Disparities, and any other relevant Federal agency, as de-
2 termined by the Director.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated \$30,000,000 for each of fiscal years
6 2021 through 2025.

7 **SEC. 4. RESEARCH WITH RESPECT TO MEDICAID COV-**
8 **ERAGE OF UTERINE FIBROIDS TREATMENT.**

9 (a) RESEARCH.—The Administrator of the Centers
10 for Medicare & Medicaid Services (referred to in this sec-
11 tion as the “Administrator”) shall expand the Chronic
12 Conditions Data Warehouse research database of such
13 Centers for Medicare & Medicaid Services to collect data
14 on items and services furnished to women diagnosed with
15 uterine fibroids and fibroids-related symptoms under a
16 State plan (or a waiver of such a plan) under the Medicaid
17 program under title XIX of the Social Security Act (42
18 U.S.C. 1396 et seq.) or under a State child health plan
19 (or a waiver of such a plan) under the Children’s Health
20 Insurance Program under title XXI of such Act (42
21 U.S.C. 1397aa et seq.) for the treatment of such fibroids
22 and symptoms for purposes of assessing the frequency at
23 which such women are furnished such items and services.

24 (b) REPORT.—

1 (1) IN GENERAL.—Not later than the date that
2 is one year after the date of the enactment of this
3 Act, the Administrator shall submit to Congress a
4 report on the amount of Federal and State expendi-
5 tures with respect to items and services furnished
6 for the treatment of uterine fibroids and fibroids-re-
7 lated symptoms under State plans (or waivers of
8 such plans) under the Medicaid program under such
9 title XIX and State child health plans (or waivers of
10 such plans) under the Children’s Health Insurance
11 Program under such title XXI.

12 (2) COORDINATION.—The Administrator shall
13 coordinate the development and submission of the
14 report required under paragraph (1) with each of
15 the following:

16 (A) Within the Centers for Medicare &
17 Medicaid Services—

18 (i) the Office of Minority Health;

19 (ii) the Center for Medicaid and
20 CHIP Services;

21 (iii) the Office of Enterprise Data and
22 Analytics; and

23 (iv) any other office or center deter-
24 mined appropriate by the Administrator.

1 (B) Any other relevant Federal agency, as
2 determined by the Administrator.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each of the fiscal years 2021 through 2025.

7 **SEC. 5. EDUCATION AND DISSEMINATION OF INFORMATION**
8 **WITH RESPECT TO UTERINE FIBROIDS.**

9 (a) UTERINE FIBROIDS PUBLIC EDUCATION PRO-
10 GRAM.—The Secretary of Health and Human Services,
11 acting through the Director of the Centers for Disease
12 Control and Prevention, shall develop and disseminate to
13 the public information regarding uterine fibroids, includ-
14 ing information on—

15 (1) the awareness, incidence, and prevalence of
16 uterine fibroids among women, including all minority
17 women;

18 (2) the elevated risk for minority women to de-
19 velop uterine fibroids; and

20 (3) the availability, as medically appropriate, of
21 the range of treatment options for symptomatic
22 uterine fibroids, including non-hysterectomy treat-
23 ments and procedures.

24 (b) DISSEMINATION OF INFORMATION.—The Sec-
25 retary may disseminate information under subsection (a)

1 directly or through arrangements with intra-agency initia-
2 tives, nonprofit organizations, consumer groups, institu-
3 tions of higher education (as defined in section 101 of the
4 Higher Education Act of 1965 (20 U.S.C. 1001)), or Fed-
5 eral, State, or local public private partnerships.

6 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this section, there are authorized
8 to be appropriated such sums as may be necessary for
9 each of fiscal years 2021 through 2025.

10 **SEC. 6. INFORMATION TO HEALTH CARE PROVIDERS WITH**
11 **RESPECT TO UTERINE FIBROIDS.**

12 (a) DISSEMINATION OF INFORMATION.—The Sec-
13 retary of Health and Human Services, acting through the
14 Administrator of the Health Resources and Services Ad-
15 ministration and the Director of the Agency for Health-
16 care Research and Quality shall, in consultation and in
17 accordance with guidelines from relevant medical societies,
18 develop and disseminate to health care providers informa-
19 tion on uterine fibroids for the purpose of ensuring that
20 health care providers remain informed about current infor-
21 mation on uterine fibroids. Such information shall include
22 the elevated risk for minority women to develop uterine
23 fibroids and the range of available options for the treat-
24 ment of symptomatic uterine fibroids, including non-
25 hysterectomy drugs and devices approved under the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
2 seq.).

3 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each of the fiscal years 2021 through 2025.

7 **SEC. 7. DEFINITION.**

8 In this Act, the term “minority women” means
9 women who are members of a racial and ethnic minority
10 group, as defined in section 1707(g) of the Public Health
11 Service Act (42 U.S.C. 300u–6(g)).

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