



House of Representatives

File No. 775

General Assembly

January Session, 2023

(Reprint of File No. 59)

Substitute House Bill No. 6672
As Amended by House Amendment
Schedule "A"

Approved by the Legislative Commissioner
May 12, 2023

AN ACT CONCERNING ENDOMETRIOSIS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- 1 Section 1. (NEW) (*Effective July 1, 2023*) (a) As used in this section:
- 2 (1) "Biorepository" means a facility that, for laboratory research,
3 collects, catalogs and stores samples of biological material from humans,
4 including, but not limited to, urine, blood, tissue, cells, DNA
5 (deoxyribonucleic acid), RNA (ribonucleic acid) and protein, that is
6 coded without individual identifiers and linked with phenotypic data;
7 and
- 8 (2) "Phenotypic data" means clinical information about a person,
9 coded without individual identifiers, that includes disease history,
10 symptoms and demographic data including, but not limited to, age, sex,
11 race and ethnicity.
- 12 (b) Not later than January 1, 2024, The University of Connecticut

13 Health Center, in collaboration with an independent, nonprofit
14 biomedical research institution in the state engaged in endometriosis
15 research with said health center, shall establish an endometriosis data
16 and biorepository program in the state to enable and promote research
17 regarding (1) early detection of endometriosis in adolescents and adults,
18 and (2) the development of therapeutic strategies to improve clinical
19 management of endometriosis.

20 (c) The endometriosis data and biorepository program established
21 pursuant to subsection (b) of this section shall:

22 (1) (A) Design a comprehensive longitudinal sample and clinical data
23 collection protocol to characterize endometriosis and cellular functions
24 of individuals with endometriosis, and (B) collect from patients with
25 endometriosis and control patients without endometriosis and code (i)
26 endometrial tissue specimens, (ii) fluids, including, but not limited to,
27 blood and urine, and (iii) clinical and demographic data and
28 questionnaires regarding symptoms of endometriosis and quality of life;

29 (2) (A) Develop standard operating procedures concerning samples
30 of biological material, including, but not limited to, transportation,
31 coding, processing, long-term retention and storage of such samples,
32 and (B) establish data transmission and onboarding operations
33 necessary for institutions in the state to participate in banking with and
34 accessing data from the data and biorepository program;

35 (3) Curate biological samples of endometriosis from a diverse cross-
36 section of communities in the state to ensure representation of all groups
37 affected by endometriosis, including such under-represented
38 populations as African American and black persons, Latino, Latina and
39 Latinx persons, Puerto Rican persons, other persons of color,
40 transgender and gender diverse persons, and persons with disabilities;

41 (4) Raise awareness regarding endometriosis in such under-
42 represented populations and promote research of better diagnostic and
43 therapeutic options, including through communications with health
44 care providers and persons impacted by endometriosis concerning

45 information about the latest therapeutic options for persons diagnosed
46 with endometriosis;

47 (5) Create opportunities for collaborative research among institutions
48 in the state focused on the pathogenesis, pathophysiology, progression,
49 prognosis and prevention of endometriosis and the discovery of
50 noninvasive diagnostic biomarkers, novel targeted therapeutics and
51 improved medical and surgical interventions;

52 (6) Serve as a centralized resource for endometriosis information and
53 a conduit to promote education and raise public awareness regarding
54 endometriosis;

55 (7) Facilitate collaboration among researchers and health care
56 providers, educators, students, patients and other individuals impacted
57 by endometriosis through conferences and continuing medical
58 education programs regarding best practices for the diagnosis, care and
59 treatment of endometriosis;

60 (8) Collect information on the impact of endometriosis on residents
61 of the state, including, but not limited to, its impact on health and
62 comorbidity, health care costs and overall quality of life; and

63 (9) Apply for and accept grants, gifts and bequests of funds for the
64 purpose of performing its functions pursuant to subdivisions (1) to (8),
65 inclusive, of this subsection.

66 (d) Not later than January 1, 2025, and annually thereafter, The
67 University of Connecticut Health Center shall report, in accordance with
68 the provisions of section 11-4a of the general statutes, to the joint
69 standing committee of the General Assembly having cognizance of
70 matters relating to public health, regarding the implementation of the
71 endometriosis data and biorepository program established pursuant to
72 subsection (b) of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>July 1, 2023</i>	New section

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 24 \$	FY 25 \$
UConn Health Ctr.	GF - Cost	220,000-468,000	225,000-735,000

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a cost to the UConn Health Center of approximately \$220,000 in FY 24 and \$225,000 in FY 25 (and annually thereafter), associated with establishing an endometriosis data and biorepository program, including research. Costs for FY 24 include: 1) \$124,000 in additional staff costs and fringe benefits, 2) \$88,000 in indirect facility and administrative costs, and 3) \$8,000 in materials and supplies. Staff costs and indirect costs increase slightly in FY 25, for a total of \$225,000.

The bill requires the UConn Health Center to establish the program in collaboration with a research laboratory within Connecticut. The bill is unclear how the costs to the private laboratory would be covered. If the cost were borne by the UConn Health Center, it is estimated that an additional state cost of \$248,000 in FY 24 and \$510,000 in FY 25 would be incurred. The additional costs in FY 24 would include: 1) \$115,000 in indirect costs, 2) \$68,000 in materials and expenses, and 3) \$65,000 in staff costs. In FY 25, the additional costs would include: 1) \$201,000 for materials, supplies and sample collection, 2) \$195,000 in facility and administrative costs, and 3) \$114,000 in staff costs. UConn Health's costs could be offset by any grants, gifts, or other funding secured for the purposes contained within the amendment.

House "A" eliminates the Endometriosis Data and Biorepository Program Oversight Committee within the Office of Legislative Management, which would have resulted in an estimated cost of \$500,000 per year beginning in FY 24.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis**sHB 6672 (as amended by House "A")******AN ACT CONCERNING ENDOMETRIOSIS.*****SUMMARY**

This bill requires UConn Health Center (UCHC), by January 1, 2024, to develop an endometriosis data and biorepository program to enable and promote research on (1) early detection of endometriosis in adolescents and adults and (2) the development of therapeutic strategies to improve clinical management of the condition. It must do this in collaboration with an independent, nonprofit biomedical research institution in Connecticut that is engaged in endometriosis research with UCHC.

Under the bill, UCHC must annually report on the program's implementation to the Public Health Committee, starting by January 1, 2025.

*House Amendment "A" (1) removes the provision creating a 16-member Endometriosis Data and Biorepository Program Oversight Committee; (2) specifies that the research institution UCHC collaborates with must be nonprofit and independent, and engaged in endometriosis research; and (3) requires UCHC, instead of the eliminated oversight committee, to annually report on the program.

EFFECTIVE DATE: July 1, 2023

ENDOMETRIOSIS DATA AND BIOREPOSITORY PROGRAM***Duties***

Under the bill, the endometriosis data and biorepository program must do the following:

1. design a comprehensive longitudinal sample and clinical data collection protocol to characterize endometriosis and cellular functions of those with endometriosis;
2. collect from patients with endometriosis and control patients without the condition and code (a) endometrial tissue specimens; (b) fluids, including blood and urine; and (c) clinical and demographic data and questionnaires on endometriosis symptoms and quality of life;
3. develop standard operating procedures for biological material samples, including for their transportation, coding, processing, and long-term retention and storage;
4. establish data transmission and onboarding operations necessary for institutions in the state to participate in banking with and accessing data from the program;
5. curate biological endometriosis samples from a diverse cross-section of communities in the state to ensure they represent all groups affected by endometriosis, including African American, black, Latino, Latina, Latinx, and Puerto Rican persons; other persons of color; transgender and gender diverse persons; and persons with disabilities;
6. raise awareness on endometriosis in these underrepresented populations and promote research on better diagnostic and therapeutic options, including through communications with health care providers and those impacted by endometriosis on information about the latest therapeutic options for people diagnosed with the condition;
7. create opportunities for collaborative research among institutions in the state focused on the pathogenesis, pathophysiology, progression, prognosis, and prevention of endometriosis and the discovery of noninvasive diagnostic biomarkers, new targeted therapeutics, and improved medical

and surgical interventions;

- 8. serve as a centralized resource for endometriosis information and a conduit to promote endometriosis education and raise its public awareness;
- 9. facilitate collaboration among researchers and health care providers, educators, students, patients, and others impacted by endometriosis through conferences and continuing medical education programs on best practices for endometriosis diagnosis, care, and treatment;
- 10. collect information on endometriosis’s impact on Connecticut residents, including health and comorbidity, health care costs, and overall quality of life; and
- 11. apply for and accept grants, gifts, and funds bequeathed to perform its functions.

Under the bill, a “biorepository” is a facility that collects, catalogs, and stores human samples of biological material, including urine, blood, tissue, cells, DNA, RNA, and protein for laboratory research. These samples are coded without individual identifiers and linked with phenotypic data (i.e., non-individually identifiable clinical information on a person’s disease history, symptoms, and demographic data, including age, sex, race, and ethnicity).

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea	35	Nay	0	(03/03/2023)
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Appropriations Committee

Joint Favorable

Yea	53	Nay	0	(05/01/2023)
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