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**ENGROSSED SUBSTITUTE SENATE BILL 5441**

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**State of Washington**

**67th Legislature**

**2021 Regular Session**

**By** Senate Health & Long Term Care (originally sponsored by Senators Wellman, Cleveland, Das, and Lovelett)

READ FIRST TIME 02/15/21.

1       AN ACT Relating to informed consent for breast implant surgery;  
2 adding a new section to chapter 18.130 RCW; and creating a new  
3 section.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5       NEW SECTION.     **Sec. 1.**     (1) The legislature finds that every  
6 person undergoing breast implant surgery should be provided complete  
7 information about potential risks, symptoms, and complications  
8 involved before the surgery.

9       (2) A survey of over 5,000 individuals who received breast  
10 implants found that 84 percent believed they were not given enough  
11 time and information to make an informed decision about the breast  
12 implant surgery.

13       (3) In October 2019, the food and drug administration recommended  
14 a warning label on all breast implants.

15       (4) Therefore, the legislature intends to require physicians to  
16 provide patients with a checklist of information and receive informed  
17 consent to empower patients to make their own choices when it comes  
18 to any risks involved in a breast implant surgery.

19       NEW SECTION.     **Sec. 2.**     A new section is added to chapter 18.130  
20 RCW to read as follows:

1 (1) Beginning January 1, 2022, during the first consultation  
2 before breast implant surgery is performed, a physician licensed  
3 under chapter 18.71 RCW or an osteopathic physician licensed under  
4 chapter 18.57 RCW must provide the patient with the following  
5 information in writing or in an electronic format:

6 (a) A description of the risks of breast implants and a  
7 description of the surgical procedures used in breast implant  
8 surgery;

9 (b) Notice that breast implants are not considered lifetime  
10 devices, the chance of developing complications increases over time,  
11 and some complications will require more surgery;

12 (c) Manufacturer patient information materials on the implants  
13 that are to be used in the surgery, including warning requirements  
14 prescribed by the United States food and drug administration;

15 (d) Information on any surgical mesh used during breast implant  
16 surgery including, but not limited to, mesh made of nondegradable  
17 synthetic materials, biodegradable synthetic materials, or animal or  
18 human derived tissues. This information must include a warning that  
19 no surgical mesh has been approved by the food and drug  
20 administration for use with breast implants;

21 (e) Information on breast implant-associated anaplastic large  
22 cell lymphoma, including notice that breast implant-associated  
23 anaplastic large cell lymphoma occurs more commonly in patients with  
24 textured breast implants than smooth implants, and deaths have  
25 occurred;

26 (f) Information on breast implant illness;

27 (g) Information on the systemic symptoms association with breast  
28 implants;

29 (h) Information on the national breast implant registry; and

30 (i) Information on how a patient can report adverse events  
31 associated with breast implants through the United States food and  
32 drug administration's medwatch program or any similar program.

33 (2) The information provided must be based on the information  
34 that is generally available to physicians who specialize in breast  
35 implant surgery.

36 (3) After providing the information required by subsection (1) of  
37 this section, a physician or osteopathic physician must obtain  
38 written informed consent for the procedure from the patient before  
39 performing the breast implant surgery.

1           (4) A violation of this section constitutes unprofessional  
2 conduct under this chapter.

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