## SUBSTITUTE SENATE BILL 5441

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 <u>NEW SECTION.</u> **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 <u>NEW SECTION.</u> **Sec. 2.** A new section is added to chapter 18.130
- 20 RCW to read as follows:

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- (1) Beginning January 1, 2022, during the first consultation before breast implant surgery is performed, a physician licensed under chapter 18.71 RCW or an osteopathic physician licensed under chapter 18.57 RCW must provide the patient with the following information in writing or in an electronic format:
- (a) A description of the risks of breast implants and a description of the surgical procedures used in breast implant surgery;
- (b) Notice that breast implants are not considered lifetime devices, the chance of developing complications increases over time, and some complications will require more surgery;
- (c) Manufacturer patient information materials on the implants that are to be used in the surgery, including warning requirements prescribed by the United States food and drug administration;
- (d) Information on breast implant-associated anaplastic large cell lymphoma, including notice that breast implant-associated anaplastic large cell lymphoma occurs more commonly in patients with textured breast implants than smooth implants, and deaths have occurred;
  - (e) Information on breast implant illness;

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- 21 (f) Information on the systemic symptoms association with breast 22 implants;
  - (g) Information on the national breast implant registry; and
  - (h) Information on how a patient can report adverse events associated with breast implants through the United States food and drug administration's medwatch program or any similar program.
  - (2) The information provided must be based on the information that is generally available to physicians who specialize in breast implant surgery.
- (3) After providing the information required by subsection (1) of 31 this section, a physician or osteopathic physician must obtain written informed consent for the procedure from the patient before 32 33 performing the breast implant surgery.
- 34 (4) A violation of this section constitutes unprofessional conduct under this chapter. 35

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