SENATE BILL REPORT
ESSB 5441

As Passed Senate, March 2, 2021

Title: An act relating to informed consent for breast implant surgery.

Brief Description: Concerning informed consent for breast implant surgery.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Wellman, Cleveland, Das and Lovelett).

Brief History:
Committee Activity: Health & Long Term Care: 2/10/21, 2/12/21 [DPS].
Floor Activity: Passed Senate: 3/2/21, 48-0.

Brief Summary of Engrossed First Substitute Bill

- Requires physicians or osteopathic physicians to provide patients with the required breast implant information and obtain informed consent before performing breast implant surgery.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5441 be substituted therefor, and the substitute bill do pass.

Signed by Senators Cleveland, Chair; Frockt, Vice Chair; Muzzall, Ranking Member; Conway, Holy, Keiser, Padden, Randall, Rivers, Robinson, Van De Wege and Wilson, J.

Staff: Ricci Crinzi (786-7253)

Background: FDA Breast Implant Guidance. Recent U.S. Food and Drug Administration (FDA) studies tracked risks associated with breast implants, including breast implant-associated anaplastic large cell lymphoma and systemic symptoms commonly referred to as breast implant illness that some patients attribute to their implants. The FDA convened a

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General and Plastic Surgery Devices Advisory Panel to discuss the long-term benefits and risks of breast implants.

On September 29, 2020, the FDA issued recommendations concerning breast implant labels to help patients make an informed decision about whether to get breast implants. The guidance provides recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants, including:

- a boxed warning for breast implants to communicate risks to patients;
- a patient decision checklist highlighting key information regarding risks should be included in a patient information booklet or brochure;
- materials and device descriptions, including types and quantities of chemicals and heavy metals found in or released by breast implants;
- silicone gel-filled breast implant rupture screening recommendations; and
- a patient device card with specific information about their breast implant product.

Informed Consent. A health care provider must obtain informed consent from a patient or the patient's representative before performing medical treatment. Informed consent is the process by which the treating health care provider discloses information to a patient or the patient's representative so the patient may make a voluntary choice to accept or refuse treatment. Informed consent generally includes a discussion of the following elements:

- the nature of the decision or procedure proposed by the provider;
- reasonable alternatives to the proposed intervention;
- the relevant risks, benefits, and uncertainties related to each alternative;
- assessment of the patient's understanding; and
- the acceptance of the intervention by the patient.

Uniform Disciplinary Act. The Uniform Disciplinary Act (UDA) is a standardized set of procedures for enforcing laws concerning licensure and misconduct of licensed health care professionals. The UDA includes the list of acts that constitute unprofessional conduct. All licensed health care professionals are subject to the UDA.

Summary of Engrossed First Substitute Bill: Beginning January 1, 2022, during the first patient consultation before breast implant surgery is performed, a licensed physician or a licensed osteopathic physician must provide the patient with the following information in writing or electronic form:

- a description of the risks associated with breast implants and a description of the surgical procedures used in breast implant surgery;
- notice that breast implants are not considered lifetime devices, and the chance of developing complications increases over time and some complications will require more surgery;
- information provided by the breast implant manufacturer concerning the implants to be used in the surgery;
- information about any surgical mesh used during the breast implant surgery;
- warning requirements issued by the FDA;

- information on breast implant-associated anaplastic large cell lymphoma, breast implant illness, and systemic symptoms associated with breast implants;
- national breast implant registry information; and
- how to report adverse events associated with breast implants through the FDA's Medwatch Program or any similar program.

The information provided to the patient must be based on the information generally available to physicians who specialize in breast implant surgery. After the physician provides the required information, the physician must obtain written informed consent for the procedure from the patient before performing breast implant surgery. A violation of any of these rules constitutes unprofessional conduct.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill: *The committee recommended a different version of the bill than what was heard.* PRO: Women need proper informed consent before breast implant surgery. Before breast implant surgery, many women did not have proper informed consent, were not explained the risks associated with this surgery, and did not receive the patient breast implant manufacturer booklet and suffered serious life changing illnesses after receiving breast implants. Some physicians told patients that breast implants were safe, and were FDA approved, yet multiple women became very sick after surgery. Some women were not aware how sick they could become from breast implants or how the implants could increase their cancer risk. If women had known in advance how sick breast implants could make them, either they would have not gotten breast implants, or if they happened to get sick after surgery, then they would have known a possible cause for their illness. Women get breast implants after breast cancer, but if they knew breast implants could cause cancer, they would not put something in their body that could cause cancer again. Women were told that breast implants were safe and lifetime devices, when this is not true. Women need full disclosure about all the risks associated with breast implants before they can make an informed decision about the procedure.

OTHER: Current statutory requirements for disclosure are broad enough to capture the informed consent requirements from this bill, so this statutory requirement might not be needed. Washington State uses the reasonable patient standard as defined in Chapter 7.70 RCW. The American Society of Plastic Surgeons has a checklist that physicians in Washington State will be encouraged to look at while discussing breast implants with patients. This discussion for breast implant informed consent could take place outside of the Legislature.

Persons Testifying: PRO: Senator Lisa Wellman, Prime Sponsor; Samantha Wellman, Samantha Pilates; Robyn Towt, BISA Breast Implant Safety Alliance; Magali Zimmermann; Terri Diaz, Breast Implant Health Summit; Renee Ridgeley, NCHR, DSLF; Krissy Espindola; Karyn Ostfeld; Diana Southern.

OTHER: Katerina LaMarche, Washington State Medical Association.

Persons Signed In To Testify But Not Testifying: No one.