S-1321.2

SUBSTITUTE SENATE BILL 5050

State of Washington 68th Legislature 2023 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Wellman, Hunt, Keiser, Kuderer, McCune, Nobles, Rolfes, Wagoner, and C. Wilson)

READ FIRST TIME 02/10/23.

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

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

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

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

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

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

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

(1) Beginning January 1, 2024, 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 information consistent with the United States federal food and drug administration breast implant safety requirements, known as the "patient decision checklist," including:

(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;

(f) Information on the systemic symptoms association with breast implants; and

(g) Information on the national breast implant registry.

(2) The following information is recommended to be provided to patients:

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

(b) 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.

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

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

(5) A violation of this section constitutes unprofessional conduct under this chapter.

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