Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

ESSB 5050

Brief Description: Concerning informed consent for breast implant surgery.

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

Brief Summary of Engrossed Substitute Bill

- Requires physicians and osteopathic physicians to provide specific information regarding risks, symptoms, and complications before breast implant surgery.

Hearing Date: 3/10/23

Staff: Emily Poole (786-7106).

Background:

Food and Drug Administration Breast Implant Guidance.

In 2021 the United States Food and Drug Administration (FDA) updated safety requirements for all approved breast implants. As part of the updated safety requirements, the FDA issued orders restricting the sale and distribution of breast implants to only health care providers and facilities that provide information to patients utilizing the "Patient Decision Checklist," a brochure that includes information on known or reported risks of breast implants. The FDA requires the brochure to be reviewed with the prospective patient, and the patient must be given the opportunity to initial and sign the Patient Decision Checklist before breast implant surgery is performed.

In 2021 the FDA also approved new labeling for all legally marketed breast implants that

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includes a boxed warning regarding the risks of breast implants, a Patient Decision Checklist, updated silicone gel-filled breast implant rupture screening recommendations, a device description with a list of specific materials used in the device, and a patient device card with specific information about the breast implant product.

Uniform Disciplinary Act.

The Uniform Disciplinary Act (UDA) provides a legal and policy framework for the regulation and oversight of health care providers by the relevant disciplining authorities for each health care profession. Under the UDA, disciplining authorities have the authority to investigate all complaints or reports of unprofessional conduct, as defined under the UDA.

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.

Summary of Bill:

Beginning January 1, 2024, a physician or osteopathic physician must provide a patient with specific information during the first consultation before a breast implant surgery is performed. The information provided to the patient must be based on the information that is generally available to physicians who specialize in breast implant surgery. The information must include:

- a description of the risks of breast implants and a description of the surgical procedures used in breast implant surgery;
- notice that breast implants are not considered lifetime devices, the chance of developing complications increases over time, and some complications will require more surgery;
- manufacturer patient information materials on the implants that are to be used, including warning requirements prescribed by the FDA;
- information on any surgical mesh used during breast implant surgery, including a warning that no surgical mesh has been approved by the FDA for use with breast implants;
- information on breast implant-associated anaplastic large cell lymphoma;
- information on breast implant illness;
- information on the systemic symptoms associated with breast implants;
- information on the national breast implant registry; and
- information on how a patient can report adverse events associated with breast implants through the FDA's Medwatch Program or any similar program.

After providing the required information, a physician or osteopathic physician must obtain written informed consent for the procedure before performing the breast implant surgery.

A violation of the requirements relating to required information and informed consent constitutes

unprofessional conduct under the UDA.

Appropriation: None.

Fiscal Note: Not requested.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.