SENATE BILL REPORT
SB 5050

As of January 17, 2023

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

Brief Description: Concerning informed consent for breast implant surgery.

Sponsors: Senators Wellman, Hunt, Keiser, Kuderer, McCune, Nobles, Rolfes, Wagoner and Wilson, C..

Brief History:
Committee Activity: Health & Long Term Care: 1/20/23.

Brief Summary of Bill

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

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Andie Parnell (786-7439)

Background: Food and Drug Administration 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 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:

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- 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.

On October 27, 2021, the FDA updated safety requirements for all approved breast implants to help those considering breast implants make informed decisions. The FDA made the following changes:

- restricted the sale and distribution of breast implants to only health care providers and facilities that provide information to patients through the Patient Decision Checklist brochure; and
- approved new labeling requirements that follow FDA's September 2020 labeling recommendations.

As of November 27, 2021, the FDA requires all breast implant manufacturers to include device-specific Patient Decision Checklist with information on known or reported risks of breast implants.

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 Bill: Beginning January 1, 2024, 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, 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: Not requested.

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

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