



**ARIZONA STATE SENATE**  
*Fifty-Fourth Legislature, Second Regular Session*

**AMENDED**  
FACT SHEET FOR S.B. 1439

breast implant surgery; informed consent

Purpose

Beginning January 1, 2021, requires a physician to provide a patient with breast implant surgery information as outlined and to obtain informed consent from the patient prior to surgery. Directs the Arizona Medical Board (AMB) and the Arizona Board of Osteopathic Examiners in Medicine and Surgery (ABOE) to convene a workgroup to develop an informed consent checklist by December 1, 2020.

Background

The U.S. Congress passed the federal Food, Drug and Cosmetic Act in 1976 granting the Food and Drug Administration (FDA) regulatory authority over breast implants which were previously unregulated. In the 1980s, breast implants were classified as Class III medical devices, and as such are required to obtain pre-market approval (PMA) and to be reviewed by the FDA for safety and effectiveness. According to the FDA, Class III medical devices have the most stringent regulatory controls and are generally devices that support or sustain human life, prevent the impairment of human health or present a potential unreasonable risk of illness or injury to the patient. Typically, a PMA submission to the FDA is required to obtain approval to market a Class III medical device; however, a few Class III medical devices are required to only have a 510(k) cleared by the FDA to be marketed. Examples of Class III medical devices that require a PMA are replacement heart valves, silicone gel-filled breast implants and implanted cerebella stimulators ([FDA](#)).

Breast implant-associated anaplastic large cell lymphoma (ALCL) was first identified in 1997. Other countries, including France and Australia, have additionally experienced reports citing a correlation between breast implants and ALCL. In 2011, the FDA issued a warning regarding ALCL in women with these medical devices, stating that such women are believed to have a small but increased risk of developing ALCL ([FDA warning](#)).

Currently, the Plastic Surgery Foundation, in collaboration with the FDA and breast implant device manufacturers, has developed the National Breast Implant Registry (NBIR) to strengthen national surveillance for breast implant devices in the United States. The purpose of the NBIR is to create a database that collects information on breast implant procedures and devices and to identify trends and other data that can be used to improve patient safety ([NBIR](#)).

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

1. Requires, beginning January 1, 2021, specified licensed physicians to provide a patient with the following breast implant surgery information prior to a breast implant surgery, either in writing or electronically, that contains:
  - a) a description of the risks of breast implants and a description of the surgical procedures used in breast implant surgery;
  - b) manufacturer patient information materials on the implants to be used in the surgery, including FDA warning requirements;
  - c) an informed consent checklist for physicians to review with the patient prior to surgery that must include information on breast implant associated ALCL, breast implant illness and the NBIR; and
  - d) information on how a patient can report adverse effects associated with breast implants through the FDA MedWatch Program.
2. Stipulates that, in addition to the breast implant surgery information requirements, a physician must obtain written informed consent from the patient before performing the surgery.
3. Directs the AMB and ABOE, by December 1, 2020, to convene a workgroup that includes licensees and patient advocates to develop an informed consent checklist and requires the workgroup to review and update the checklist as necessary.
4. Classifies, as unprofessional conduct, knowingly violating the breast implant surgery information and informed consent requirements and subjects the physician to license suspension or revocation.
5. Becomes effective on the general effective date.

Amendments Adopted by Committee

1. Applies informed consent requirements beginning January 1, 2021.
2. Requires the AMB and ABOE to convene a workgroup to develop an informed consent checklist by December 1, 2020.
3. Modifies specified information that must be provided to a patient prior to breast implant surgery.

Senate Action

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Prepared by Senate Research

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CRS/kja