ARIZONA HOUSE OF REPRESENTATIVES

Fifty-fifth Legislature
First Regular Session

Senate: HHS DP 8-0-0-0 | 3rd Read 30-0-0-0
House: HHS DP 8-0-1-0

SB 1001: breast implant surgery; informed consent
Sponsor: Senator Ugenti-Rita, LD 23
House Engrossed

Overview
Requires a licensed physician to provide a patient with breast implant information and obtain the patient's informed consent prior to the surgery.

History
The Federal Food, Drug and Cosmetic Act, authorizes the Food and Drug Administration (FDA) to regulate medical devices and cosmetics, including breast implants. Today, breast implants are classified as Class III medical devices which are required to obtain premarket approval and be reviewed by the FDA in order to determine their safety and effectiveness.

MedWatch is the FDA's medical product safety reporting system which publishes safety alerts for FDA-regulated products and allows health professionals and patients to report adverse medical events.

Provisions
1. Requires, beginning January 1, 2022, a licensed physician to provide a patient, in either writing or an electronic format and prior to breast implant surgery, with the following:
   a) A description of the risks of breast implants and of the surgical procedures used in breast implant surgery;
   b) Manufacturer patient information materials on the implants that will be used in the surgery, including warning requirements prescribed by the FDA;
   c) An informed consent checklist that includes information on breast implant-associated anaplastic large cell lymphoma, breast implant illness and the National Breast Implant Registry (NBIR); and
   d) Information on how the patient can report adverse events associated with breast implants the FDA MedWatch Program. (Sec. 1)
2. Requires physicians to obtain written informed consent from a patient before performing breast implant surgery. (Sec. 1)
3. Specifies that a physician who knowingly violates the breast implant surgery information and informed consent requirements commits an act of unprofessional conduct and is subject to disciplinary action. (Sec. 1)
4. Directs the Arizona Medical Board (AMB) and the Arizona Board of Osteopathic Examiners in Medicine and Surgery (ABOE) to convene a workgroup, by December 1, 2021, that includes licensees and patient advocates in order to develop and update, as necessary, an informed consent checklist for physicians to discuss with patients before implant surgery. (Sec. 1)

☐ Prop 105 (45 votes) ☐ Prop 108 (40 votes) ☐ Emergency (40 votes) ☐ Fiscal Note

5. Defines *breast implant surgery* as the surgical placement of a cosmetic breast implant. (Sec. 1)