

Senate Engrossed

breast implant surgery; informed consent

State of Arizona
Senate
Fifty-fifth Legislature
First Regular Session
2021

SENATE BILL 1001

AN ACT

AMENDING TITLE 32, CHAPTER 32, ARTICLE 1, ARIZONA REVISED STATUTES, BY
ADDING SECTION 32-3228; RELATING TO HEALTH CARE PROFESSIONALS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Title 32, chapter 32, article 1, Arizona Revised
3 Statutes, is amended by adding section 32-3228, to read:

4 32-3228. Informed consent; breast implant surgery;
5 requirements; unprofessional conduct; work group;
6 definition

7 A. BEGINNING JANUARY 1, 2022, BEFORE PERFORMING BREAST IMPLANT
8 SURGERY, A PHYSICIAN WHO IS LICENSED PURSUANT TO CHAPTER 13 OR 17 OF THIS
9 TITLE MUST PROVIDE THE PATIENT WITH THE FOLLOWING, IN WRITING OR IN AN
10 ELECTRONIC FORMAT, BASED ON THE INFORMATION THAT IS THEN GENERALLY
11 AVAILABLE TO PHYSICIANS WHO PERFORM BREAST IMPLANT SURGERY:

12 1. A DESCRIPTION OF THE RISKS OF BREAST IMPLANTS AND OF THE
13 SURGICAL PROCEDURES USED IN BREAST IMPLANT SURGERY.

14 2. MANUFACTURER PATIENT INFORMATION MATERIALS, IN A HARD COPY OR AN
15 ELECTRONIC FORMAT, ON THE IMPLANTS THAT WILL BE USED IN THE SURGERY,
16 INCLUDING WARNING REQUIREMENTS PRESCRIBED BY THE UNITED STATES FOOD AND
17 DRUG ADMINISTRATION.

18 3. THE INFORMED CONSENT CHECKLIST DEVELOPED PURSUANT TO SUBSECTION
19 D OF THIS SECTION THAT INCLUDES, AT A MINIMUM, INFORMATION ON:

- 20 (a) BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA.
- 21 (b) BREAST IMPLANT ILLNESS.
- 22 (c) THE NATIONAL BREAST IMPLANT REGISTRY.

23 4. INFORMATION ON HOW THE PATIENT CAN REPORT ADVERSE EVENTS
24 ASSOCIATED WITH BREAST IMPLANTS THROUGH THE UNITED STATES FOOD AND DRUG
25 ADMINISTRATION'S MEDWATCH PROGRAM OR ANY SIMILAR PROGRAM.

26 B. A PHYSICIAN MUST PROVIDE THE INFORMATION REQUIRED BY SUBSECTION
27 A OF THIS SECTION AND OBTAIN WRITTEN INFORMED CONSENT FOR THE PROCEDURE
28 FROM THE PATIENT BEFORE PERFORMING THE BREAST IMPLANT SURGERY.

29 C. A PHYSICIAN WHO KNOWINGLY VIOLATES THIS SECTION COMMITS AN ACT
30 OF UNPROFESSIONAL CONDUCT AND IS SUBJECT TO DISCIPLINARY ACTION.

31 D. ON OR BEFORE DECEMBER 1, 2021, THE ARIZONA MEDICAL BOARD AND THE
32 ARIZONA BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY SHALL
33 CONVENE A WORK GROUP THAT INCLUDES LICENSEE REPRESENTATIVES AND PATIENT
34 ADVOCATES TO JOINTLY DEVELOP AN INFORMED CONSENT CHECKLIST FOR PHYSICIANS
35 TO DISCUSS WITH PATIENTS BEFORE BREAST IMPLANT SURGERY. THE INFORMED
36 CONSENT CHECKLIST SHALL INCLUDE THE INFORMATION PRESCRIBED IN SUBSECTION A
37 OF THIS SECTION AND ANY OTHER INFORMATION THE BOARDS AND THE WORK GROUP
38 DETERMINE TO BE NECESSARY. THE WORK GROUP SHALL REVIEW THE CHECKLIST AND
39 PROVIDE UPDATES AS NECESSARY.

40 E. FOR THE PURPOSES OF THIS SECTION, "BREAST IMPLANT SURGERY" MEANS
41 THE SURGICAL PLACEMENT OF A COSMETIC BREAST IMPLANT.