

**Representative David Ure** proposes to substitute the following bill:

**BREAST IMPLANT SURGERY**

2000 GENERAL SESSION

STATE OF UTAH

**Sponsor: David Ure**

AN ACT RELATING TO HEALTH; DEFINING TERMS; REQUIRING THE DEPARTMENT OF HEALTH TO PREPARE AN INFORMED CONSENT FORM FOR BREAST IMPLANT SURGERY; REQUIRING HEALTH CARE PROVIDERS TO PROVIDE INFORMED CONSENT BEFORE PERFORMING A BREAST IMPLANT SURGERY; AND MAKING CONFORMING AMENDMENTS.

This act affects sections of Utah Code Annotated 1953 as follows:

AMENDS:

**26-21-11**, as last amended by Chapter 209, Laws of Utah 1997

**26-21a-101**, as enacted by Chapter 126, Laws of Utah 1991

**58-67-502**, as enacted by Chapter 248, Laws of Utah 1996

**58-68-502**, as enacted by Chapter 248, Laws of Utah 1996

ENACTS:

**26-21a-401**, Utah Code Annotated 1953

**26-21a-402**, Utah Code Annotated 1953

**26-21a-403**, Utah Code Annotated 1953

**26-21a-404**, Utah Code Annotated 1953

*Be it enacted by the Legislature of the state of Utah:*

Section 1. Section **26-21-11** is amended to read:

**26-21-11. Violations -- Denial or revocation of license -- Restricting or prohibiting new admissions -- Monitor.**

If the department finds a violation of this chapter, Section 26-21a-403, or any rules adopted

26 pursuant to this chapter the department may take one or more of the following actions:

27 (1) serve a written statement of violation requiring corrective action, which shall include  
28 time frames for correction of all violations;

29 (2) deny or revoke a license if it finds:

30 (a) there has been a failure to comply with the rules established pursuant to this chapter;

31 (b) evidence of aiding, abetting, or permitting the commission of any illegal act; or

32 (c) conduct adverse to the public health, morals, welfare, and safety of the people of the  
33 state;

34 (3) restrict or prohibit new admissions to a health care facility or revoke the license of a  
35 health care facility for:

36 (a) violation of any rule adopted under this chapter; or

37 (b) permitting, aiding, or abetting the commission of any illegal act in the health care  
38 facility;

39 (4) place a department representative as a monitor in the facility until corrective action is  
40 completed;

41 (5) assess to the facility the cost incurred by the department in placing a monitor;

42 (6) assess an administrative penalty as allowed by Subsection 26-23-6(1)(a); or

43 (7) issue a cease and desist order to the facility.

44 Section 2. Section **26-21a-101** is amended to read:

45 **CHAPTER 21a. WOMEN'S HEALTH**

46 **Part 1. Definitions**

47 **26-21a-101. Definitions.**

48 As used in this chapter:

49 (1) "Breast implant surgery" means a medical procedure designed to reconstruct or  
50 augment the size of a patient's breast by means of an implant.

51 [(1)] (2) "Breast cancer screening mammography" means a standard two-view per breast,  
52 low-dose as defined by the National Cancer Institute, radiographic examination of the breasts to  
53 detect unsuspected breast cancer using equipment designed and dedicated specifically for  
54 mammography.

55 [(2)] (3) "Diagnostic mammography" means mammography performed on a woman having  
56 suspected breast cancer.

57 ~~[(3)]~~ (4) "Facility" means a facility that provides screening or diagnostic breast  
58 mammography services.

59 (5) "Implant" means any object or substance that:

60 (a) is foreign to the patient's body;

61 (b) is purposefully left in a patient's chest cavity in connection with a breast implant  
62 surgery; and

63 (c) is not intended or designed to be absorbed into the patient's body.

64 (6) "Patient" means a person who is considering or undergoes a breast implant surgery.

65 Section 3. Section **26-21a-401** is enacted to read:

66 **Part 4. Breast Implant Surgery Act**

67 **26-21a-401. Title.**

68 This part is known as the "Breast Implant Surgery Act."

69 Section 4. Section **26-21a-402** is enacted to read:

70 **26-21a-402. Duties of the department.**

71 (1) The department shall prepare an informed consent form for breast implant surgery.

72 (2) (a) The informed consent form for breast implant surgery shall require that the  
73 following information be given to a patient:

74 (i) the chemical make up of any implant to be used;

75 (ii) the name of the manufacturer and any bin, lot number, and other related identifying  
76 information associated with any implant to be used;

77 (iii) the potential risks of breast implant surgery based on:

78 (A) the best, available research; and

79 (B) any state-specific health data;

80 (iv) the statistical chances of an adverse result;

81 (v) the potential warning signs associated with an adverse result; and

82 (vi) a telephone number and address that the patient can use to contact the department in  
83 the event that the patient believes that an adverse result may have occurred.

84 (3) The department shall make available:

85 (a) the informed consent form prepared under Subsection (2); and

86 (b) any federal Food and Drug Administration-prepared consumer materials on breast  
87 implants that the department selects for patient distribution.

88 (4) In preparing the consent form, the department may seek the input of:  
89 (a) the Utah Medical Association;  
90 (b) the Utah Hospital Association;  
91 (c) one or more women who have undergone breast implant surgery; and  
92 (d) others who, in the opinion of the department, may be able and willing to provide  
93 helpful information or insight on breast implant surgery.

94 Section 5. Section **26-21a-403** is enacted to read:

95 **26-21a-403. Duties of health care providers and facilities.**

96 (1) At the initial consultation for breast implant surgery, and in no event less than 24 hours  
97 before the surgery is performed, the patient's health care provider shall:

98 (a) give the patient the informed consent form for breast implant surgery prepared by the  
99 department and any federal Food and Drug Administration-prepared consumer materials on breast  
100 implants that the department has selected for patient distribution;

101 (b) thoroughly explain the provisions of the informed consent form; and

102 (c) a brief description of the training and experience of the provider relevant to breast  
103 implant surgery.

104 (2) Before a breast implant surgery may be performed within a health care facility, the  
105 facility shall verify that:

106 (a) the informed consent has been obtained from the patient in accordance with Subsection  
107 (1); and

108 (b) the patient has signed the form.

109 Section 6. Section **26-21a-404** is enacted to read:

110 **26-21a-404. Failure to comply.**

111 The failure of a health care provider or health care facility to comply with the provisions  
112 of this chapter may be grounds for disciplinary action for unprofessional conduct against the  
113 license of the provider pursuant to Title 58, Occupations and Professions, or facility pursuant to  
114 Chapter 21, Health Care Facility Licensing and Inspection Act.

115 Section 7. Section **58-67-502** is amended to read:

116 **58-67-502. Unprofessional conduct.**

117 "Unprofessional conduct" includes, in addition to the definition in Section 58-1-501 and  
118 a violation of the informed consent requirement of Section 26-21a-403, using or employing the

119 services of any individual to assist a licensee in any manner not in accordance with the generally  
120 recognized practices, standards, or ethics of the profession, state law, or division rule.

121 Section 8. Section **58-68-502** is amended to read:

122 **58-68-502. Unprofessional conduct.**

123 "Unprofessional conduct" includes, in addition to the definition in Section 58-1-501 and  
124 a violation of the informed consent requirement of Section 26-21a-403, using or employing the  
125 services of any individual to assist a licensee in any manner not in accordance with the generally  
126 recognized practices, standards, or ethics of the profession, state law, or division rule.