LEGISLATIVE GENERAL COUNSEL
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H.B. 229

BREAST IMPLANT SURGERY

2000 GENERAL SESSION

STATE OF UTAH

Sponsor: David Ure

AN ACT RELATING TO HEALTH; DEFINING TERMS; IMPOSING DUTIES ON THE DEPARTMENT OF HEALTH TO PREPARE AN INFORMED CONSENT FORM FOR BREAST IMPLANT SURGERY, A POST-SURGERY REPORT, AND A POST-SURGERY SURVEY; REQUIRING HEALTH CARE PROVIDERS TO PROVIDE INFORMED CONSENT BEFORE PERFORMING A BREAST IMPLANT SURGERY; REQUIRING HEALTH CARE FACILITIES TO SUBMIT A POST-SURGERY REPORT TO THE DEPARTMENT OF HEALTH; 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER 21a. WOMEN'S HEALTH

Part 1. Definitions

26-21a-101. Definitions.

As used in this chapter:

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

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

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

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

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

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

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

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

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

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

Part 4. Breast Implant Surgery Act

26-21a-401. Title.

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

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

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

(1) The department shall prepare:

(a) an informed consent form for breast implant surgery;

(b) a post-breast implant surgery report; and

(c) a post-breast implant survey.

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

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

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

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

(A) the best, available research;

(B) state-specific health data; and

(C) information regarding breast implants published by the federal Food and Drug Administration;

(iv) the statistical chances of an adverse result;

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

(vi) a telephone number to call in the event the patient believes that an adverse result may

have occurred.

(b) In addition to the requirements of Subsection (2)(a), an informed consent form for breast implant surgery shall request the permission of the patient to forward the patient's name to the department for future follow-up on the patient's health status.

(3) The post-breast implant surgery report shall record the following information for a patient who has undergone a breast implant surgery:

(a) the date on which informed consent was given, explained, and signed;

(b) the date on which the surgery was performed;

(c) the name of the manufacturer of any implant left in the body of the patient;

(d) the lot number, bin number, and other related identifying information associated with any implant left in the body of the patient; and

(e) the name and address of the patient if the patient consented to follow-up contact by the department.

(4) The post-breast implant survey shall be designed as a follow-up tool for determining the ongoing health status of patients who have undergone breast implant surgery.

(5) (a) The department shall distribute informed consent forms for breast implant surgery and post-breast implant reports to health care providers and facilities.

(b) The department shall, in its discretion, distribute post-breast implant surveys to patients.

(6) The department shall use the information produced from the post-implant surveys:

(a) in preparing the informed consent form for breast implant surgery;

(b) to inform women generally regarding the health issues associated with breast implant surgery;

(c) to track the long-term health status of women who have undergone breast implant surgery; and

(d) for other health-related purposes identified by the department.

(7) In preparing the forms, reports, and surveys required by Subsection (1), the department shall seek the input of:

(a) the Utah Medical Association;

(b) the Utah Hospital Association;

(c) one or more women who have undergone breast implant surgery; and

(d) others who, in the opinion of the department, may be able and willing to provide helpful information or insight on breast implant surgery.

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

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

(1) At the initial consultation for breast implant surgery, and in no event less than 72 hours before the surgery is performed, the patient's health care provider shall:

(a) give the patient the informed consent form for breast implant surgery prepared by the department; and

(b) thoroughly explain the provisions of the informed consent form.

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

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

(b) the patient has signed the form.

(3) After a breast implant surgery has been performed, the health care facility shall:

(a) fill out the post-breast augmentation surgery report; and

(b) send the report and a copy of the patient's signed informed consent to the department within 30 days of the surgery unless an extension of time is requested.

(4) The health care provider that obtained the patient's informed consent and performed the surgery shall cooperate with the health care facility in filling out the post-breast augmentation surgery report.

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

26-21a-404. Failure to comply.

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

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

58-67-502. Unprofessional conduct.

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

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

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

58-68-502. Unprofessional conduct.

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

Legislative Review Note
as of 1-14-00 7:15 AM

A limited legal review of this legislation raises no obvious constitutional or statutory concerns.

Office of Legislative Research and General Counsel