

Senate File 4 - Introduced

SENATE FILE 4
BY ZAUN

A BILL FOR

1 An Act relating to the provision of informed consent prior
2 to breast implant surgery, and providing for professional
3 discipline.

4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 147.115 Prior informed consent —
2 breast implant surgery.

3 1. Prior to performing breast implant surgery, a physician
4 who is licensed pursuant to chapter 148 shall provide the
5 patient with the following, in writing or in an electronic
6 format, based on information generally available at the time of
7 the surgery to physicians who perform breast implant surgery:

8 a. A description of the risks of breast implants and of the
9 surgical procedures used in breast implant surgery.

10 b. Manufacturer patient information materials, in a hard
11 copy or an electronic format, for the implants that will be
12 used in the surgery including warning requirements prescribed
13 by the United States food and drug administration.

14 c. The informed consent checklist developed under this
15 section that includes, at a minimum, information on all of the
16 following:

17 (1) Breast implant-associated anaplastic large cell
18 lymphoma.

19 (2) Breast implant illness.

20 (3) The national breast implant registry.

21 (4) Information for the patient to use in reporting adverse
22 events associated with breast implants through the United
23 States food and drug administration's Medwatch program or any
24 similar medical product safety reporting program for health
25 professionals, patients, and consumers.

26 2. A physician shall obtain written certification from the
27 patient that the patient has received the information required
28 under subsection 1 prior to performing the breast implant
29 surgery.

30 3. A physician who violates this section commits
31 unprofessional conduct and is subject to professional
32 disciplinary provisions.

33 4. The board of medicine shall convene a work group that
34 includes physician representatives and patient advocates to
35 jointly develop an informed consent checklist for physicians

1 to discuss with patients prior to breast implant surgery.
2 The informed consent checklist shall include, at a minimum,
3 the information prescribed in subsection 1 and any other
4 information the board of medicine and the work group determine
5 necessary. The work group shall review the checklist and
6 provide updates as necessary.

7 5. For the purposes of this section, "*breast implant*
8 *surgery*" means the surgical placement of a breast implant for
9 cosmetic or reconstructive purposes.

10 EXPLANATION

11 The inclusion of this explanation does not constitute agreement with
12 the explanation's substance by the members of the general assembly.

13 This bill requires the provision of informed consent prior
14 to breast implant surgery.

15 Under the bill, a licensed physician shall provide the
16 patient, in writing or in an electronic format, based on
17 information generally available at the time of the surgery to
18 physicians who perform breast implant surgery: a description
19 of the risks of breast implants and of the surgical procedures
20 used in breast implant surgery; manufacturer patient
21 information materials for the implants that will be used in the
22 surgery including warning requirements prescribed by the United
23 States food and drug administration (FDA); the informed consent
24 checklist developed under the bill; and information for the
25 patient to report adverse events to the FDA's Medwatch program
26 or any similar medical product safety reporting program for
27 health professionals, patients, and consumers.

28 A physician shall obtain written certification from the
29 patient that the patient has received the information specified
30 under the bill prior to performing the breast implant surgery.

31 A physician who violates the bill commits unprofessional
32 conduct and is subject to professional disciplinary provisions.

33 The bill requires the board of medicine to convene a
34 work group, including physician representatives and patient
35 advocates, to jointly develop an informed consent checklist for

1 physicians to discuss with patients prior to breast implant
2 surgery. The work group shall review the checklist and provide
3 updates as necessary.

4 Under the bill, "breast implant surgery" means the surgical
5 placement of a breast implant for cosmetic or reconstructive
6 purposes.