

ASSEMBLY, No. 5802

STATE OF NEW JERSEY 219th LEGISLATURE

INTRODUCED JUNE 1, 2021

Sponsored by:

Assemblyman JOHN F. MCKEON

District 27 (Essex and Morris)

SYNOPSIS

Requires informed consent for breast implant surgery.

CURRENT VERSION OF TEXT

As introduced.



1 **AN ACT** concerning informed consent for breast implant surgery
2 and supplementing Title 45 of the Revised Statutes.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. a. As used in this section:

8 “Breast implant surgery” means the surgical placement of a
9 cosmetic breast implant.

10 “Physician” means an individual licensed to practice medicine
11 and to perform breast implant surgery in this State.

12 b. Before performing breast implant surgery, a physician shall
13 provide information to a patient, in writing or in an electronic
14 format, that includes, but is not limited to:

15 (1) a description of the risks of breast implants and of the
16 surgical procedures used in breast implant surgery;

17 (2) manufacturer patient information materials, in written or
18 electronic format, on the implants that will be used in the surgery
19 including warning requirements prescribed by the United States
20 Food and Drug Administration;

21 (3) a Global Patient Advocacy Coalition standardized informed
22 consent checklist based on recommendations by the United States
23 Food and Drug Administration’s guidance on breast implants,
24 which includes, at a minimum:

25 (a) information on breast implant-associated anaplastic large
26 cell lymphoma;

27 (b) information on breast implant illness;

28 (c) information on the systematic symptoms associated with
29 breast implants; and

30 (d) information on the national breast implant registry; and

31 (4) information on how the patient can report adverse events
32 associated with breast implants through the United States Food and
33 Drug Administration’s MedWatch program or any other similar
34 medical product safety reporting program.

35 c. A physician shall furnish the information required by
36 subsection b. of this section to the patient and obtain written
37 informed consent for the procedure from the patient before
38 performing the breast implant surgery.

39 d. A physician who knowingly violates the requirements of this
40 section commits an act of unprofessional conduct and shall be
41 subject to disciplinary action, which may include license suspension
42 or revocation.

43
44 2. The Commissioner of Health, pursuant to the
45 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-
46 1 et seq.), shall promulgate rules and regulations to effectuate the
47 provisions of this act.

1 3. This act shall take effect immediately.

2

3

4

STATEMENT

5

6 This bill requires a physician to provide information about breast
7 implant surgery to a patient and to obtain written informed consent
8 for the procedure from the patient before performing breast implant
9 surgery. The information will be provided to the patient in writing
10 or in an in electronic format, and will include, but is not limited to:
11 a description of the risks of breast implants and of the surgical
12 procedures used in breast implant surgery; manufacturer patient
13 information materials on the implants that will be used in the
14 surgery including warning requirements prescribed by the United
15 States Food and Drug Administration; a Global Patient
16 Advocacy Coalition standardized informed consent checklist based
17 on recommendations by the United States Food and Drug
18 Administration's guidance on breast implants; and information on
19 how the patient can report adverse events associated with breast
20 implants. A physician who knowingly violates the requirements of
21 this bill commits an act of unprofessional conduct and will be
22 subject to disciplinary action, which may include license suspension
23 or revocation.