SENATE, No. 3606

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED APRIL 19, 2021

Sponsored by:
Senator JOSEPH PENNACCHIO
District 26 (Essex, Morris and Passaic)
Senator JOSEPH F. VITALE
District 19 (Middlesex)

Co-Sponsored by:
Senator Oroho

SYNOPSIS

Requires informed consent for breast implant surgery.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 6/15/2021)

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

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

1. a. As used in this section:

"Breast implant surgery" means the surgical placement of a cosmetic breast implant.

"Physician" means an individual licensed to practice medicine and to perform breast implant surgery in this State.

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

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

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

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

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

(b) information on breast implant illness;

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

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

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

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

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

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

3. This act shall take effect immediately.

STATEMENT

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