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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 762 Session of 2021

INTRODUCED BY J. WARD, COSTA, YUDICHAK, MENSCH AND MUTH, JUNE 16, 2021

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, JUNE 16, 2021

AN ACT

Amending the act of March 20, 2002 (P.L.154, No.13), entitled "An act reforming the law on medical professional liability; providing for patient safety and reporting; establishing the Patient Safety Authority and the Patient Safety Trust Fund; abrogating regulations; providing for medical professional liability informed consent, damages, expert qualifications, limitations of actions and medical records; establishing the Interbranch Commission on Venue; providing for medical professional liability insurance; establishing the Medical Care Availability and Reduction of Error Fund; providing for medical professional liability claims; establishing the Joint Underwriting Association; regulating medical professional liability insurance; providing for medical licensure regulation; providing for administration; imposing penalties; and making repeals," in medical professional liability, providing for enhanced information on breast implants.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of March 20, 2002 (P.L.154, No.13), known as the Medical Care Availability and Reduction of Error (Mcare) Act, is amended by adding a section to read:

Section 504.1. Enhanced information on breast implants.

(a) Physician duty.--During the first consultation between a physician and patient before breast implant surgery is

performed, the physician shall provide the patient with the following information in writing or in an electronic format:

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

(2) Notice that breast implants are not considered lifetime devices, the chance of developing complications increases over time and some complications will require more surgery.

(3) Manufacturer patient information materials on the implants that are to be used in the surgery, including warning requirements prescribed by the Food and Drug Administration.

(4) Information on surgical mesh used during breast implant surgery including mesh made of nondegradable synthetic materials, biodegradable synthetic materials or animal or human derived tissues. The information shall include a warning that no surgical mesh has been approved by the Food and Drug Administration for use with breast implants.

(5) Information on breast implant-associated anaplastic large cell lymphoma, including notice that breast implant-associated anaplastic large cell lymphoma occurs more commonly in patients with textured breast implants than smooth implants and that deaths have occurred.

(6) Information on breast implant illness, with the use of the breast implant patient checklist described in subsection (d).

(7) Information on the systemic symptoms associated with breast implants.

(8) Information on the national breast implant registry.

(9) Information on how a patient can report adverse events associated with breast implants through the Food and Drug Administration's MedWatch program or similar program.

(b) Breast implant information.--The information provided under subsection (a) shall be based on the information that is generally available to physicians who specialize in breast implant surgery.

(c) Informed consent.--After providing the information required under subsection (a), a physician shall obtain written informed consent for the procedure from the patient before performing the breast implant surgery.

(d) Breast implant patient checklist.--The department shall transmit notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin of the breast implant patient checklist, and any change to the breast implant patient checklist shall be transmitted by the department separately as a notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. The department shall publish and maintain the complete breast implant patient checklist on the department's publicly accessible Internet website.

(e) Violation.--A violation of this section constitutes unprofessional conduct under the the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act, and the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.

(f) Definitions.--As used in this section, the following words and phrases shall have the meanings given to them in this subsection unless the context clearly indicates otherwise:

"Breast implant patient checklist." A standardized informed

consent checklist developed by an international group of professional societies and patient advocacy organizations, based on recommendations by the Food and Drug Administration's guidance on breast implants, that includes information relating to:

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

(2) Breast implant illness.

(3) The systematic symptoms associated with breast implants.

(4) The national breast implant registry.

"Breast implant surgery." The surgical placement of a cosmetic breast implant.

"Department." The Department of State of the Commonwealth.

"National breast implant registry." A database established by a national organization of plastic surgeons in the United States, in collaboration with the Food and Drug Administration, patients and breast implant manufacturers that:

(1) is designed to strengthen the postmarket surveillance infrastructure for current and future breast implant devices in the United States; and

(2) is a quality improvement initiative and safety surveillance registry that collects clinical, procedural and outcomes data at the time of operation and subsequent reoperations for patients receiving breast implants in the United States.

"Physician." An individual who is licensed to practice medicine and perform breast implant surgery in this Commonwealth.

Section 2. This act shall take effect January 1, 2022, or

immediately, whichever is later.