HOUSE BILL NO. 4298

March 25, 2025, Introduced by Reps. O'Neal, Young, Neeley, Longjohn, Byrnes, Martus, Glanville and Scott and referred to Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding sections 17019 and 17519.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17019. (1) Beginning January 1, 2026, a physician shall not perform breast implant surgery on a patient without first providing the patient with and discussing all of the following and obtaining the patient's written, informed consent:

(a) A description of the risks associated with breast implants

and a description of the surgical procedure used in breast implant surgery.

(b) Manufacturer patient information materials on the breast implant that will be used in the breast implant surgery, including, but not limited to, warning requirements prescribed by the United States Food and Drug Administration.

(c) The informed consent checklist described in subsection (3).

(d) Information on how the patient can report an adverse event associated with a breast implant through the United States Food and Drug Administration's medical product safety reporting program or a similar program approved by the board.

(2) The information described in subsection (1) must be provided to the patient at an initial consultation for breast implant surgery either in writing or in electronic form. The information described in subsection (1) must be based on information that is generally available to physicians who specialize in breast implant surgery at the time the information is provided to the patient.

(3) By December 31, 2025, the board, in consultation with the Michigan board of osteopathic medicine and surgery and patient advocacy groups, shall develop or adopt an informed consent checklist. The board shall periodically review the informed consent checklist to determine whether an update to the checklist is necessary and develop or adopt an updated informed consent checklist as it determines necessary or appropriate. The informed consent checklist must include all of the following information:

(a) Information on breast implant-associated anaplastic large cell lymphoma, squamous cell carcinoma, B-cell lymphoma, T-cell

lymphoma, melanoma, and any other cancer that may be caused by breast implants.

(b) Information on breast implant illness.

(c) Information on the Plastic Surgery Foundation's National Breast Implant Registry or a similar registry approved by the boards described in this subsection.

(d) A statement indicating that the United States Food and Drug Administration has issued a black box warning on breast implant packaging.

(e) Any other information that is considered necessary or appropriate.

(4) As used in this section, "breast implant surgery" means the surgical placement of a cosmetic breast implant.

Sec. 17519. (1) Beginning January 1, 2026, a physician shall not perform breast implant surgery on a patient without first providing the patient with and discussing all of the following and obtaining the patient's written, informed consent:

(a) A description of the risks associated with breast implants and a description of the surgical procedure used in breast implant surgery.

(b) Manufacturer patient information materials on the breast implant that will be used in the breast implant surgery, including, but not limited to, warning requirements prescribed by the United States Food and Drug Administration.

(c) The informed consent checklist described in section 17019.

(d) Information on how the patient can report an adverse event associated with a breast implant through the United States Food and Drug Administration's medical product safety reporting program or a similar program approved by the board.

(2) The information described in subsection (1) must be provided to the patient at an initial consultation for breast implant surgery either in writing or in electronic form. The information described in subsection (1) must be based on information that is generally available to physicians who specialize in breast implant surgery at the time the information is provided to the patient.

(3) As used in this section, "breast implant surgery" means the surgical placement of a cosmetic breast implant.