AN ACT Relating to informed consent for breast implant surgery;
BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF [STATE]:

Sec. 1. FINDINGS

(1) The legislature finds that every person undergoing breast implant surgery should be provided before the surgery complete information about potential risks, symptoms, and complications involved.

(2) Surveys of individuals who received breast implants have consistently found that very high percentages believed they were not given enough time and information to make an informed decision about the breast implant surgery.

(3) In October 2019, the United States Food and Drug Administration recommended a black box warning label on all breast implants.

(4) Therefore, the legislature intends to require physicians to ensure breast implant patients achieve informed consent and to empower patients to make their own choices when it comes to any risks involved in a breast implant surgery by providing patients with a decision checklist and related information in addition their standard surgical and breast implant surgery informed consent process.

Sec. 2. [STATE] BREAST IMPLANT PATIENT DECISION CHECKLIST

(1) Beginning [EFFECTIVE DATE], during the first consultation, before an allopathic physician licensed under [CODE CITATION]or an osteopathic physician licensed under [CODE CITATION] performs breast implant surgery, they must at minimum provide the patient with, in writing or in an electronic format, the [STATE] Breast Implant Surgery Patient Decision Checklist and the additional information listed in Subsection 2(3).

(2)The [STATE] Breast Implant Surgery Patient Decision Checklist must always contain:

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

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

(c) information on breast implant illness;

(d) information on the National Breast Implant Registry;

(e) information on how a patient can report adverse events associated with breast implants through the United States Food and Drug Administration's MedWatch program or any similar program; and

(3)In addition to the [STATE] Breast Implant Surgery Patient Decision Checklist, physicians must provide patients at the same time as the checklist:

(a) manufacturer patient information materials on the implants that are to be used in the surgery, including and

(b)all warning requirements prescribed or recommended by the United States Food and Drug Administration that are not duplicative with those already provided through the checklist.

(4)By [EFFECTIVE DATE MINUS 90 DAYS], the [STATE MEDICAL BOARD(S)] must post the [STATE] Breast Implant Surgery Patient Decision Checklist to its website and communicate the informed consent requirements under Subsections 2(1)-(3) to the state's physicians. The [STATE MEDICAL BOARD(S)]shall post, maintain, and publicize the checklist in perpetuity.

(4) By [EFFECTIVE DATE PLUS 90 DAYS], the [STATE MEDICAL BOARD(S)] must convene a work group to review and maintain the [STATE] Breast Implant Surgery Patient Decision Checklist. The work group shall convene to review the checklist before [EFFECTIVE DATE PLUS ONE YEAR] and must meet at least annually every year thereafter. The work group should review and maintain the checklist based on the current surgical procedures available, the current evidence-based understanding of implant-associated illnesses, and the current post-market surveillance and adverse event reporting infrastructure. The work group must consist of patient advocates and licensed allopathic or osteopathic physicians with experience in advanced implant-based breast reconstruction techniques.

(5)The initial [STATE] Breast Implant Patient Decision Checklist shall say:

(INSERT CHECKLIST)

(6) After providing the information required by subsections 2(1)-(3), a physician or osteopathic physician must obtain written informed consent for the procedure from the patient before performing the breast implant surgery.

Sec. 3. ENFORCEMENT

(1) A physician who violates any of subsections 2(1)-(6) shall be required to complete [XX] hours of AMA PRA Category 1 or AOA Category 2-A patient safety continuing medical education in addition to any required to maintain state licensure. This continuing medical

education must be related to patient-facing communication, breast implant safety, or breast implant associated cancers and illnesses.

(2)The violating physician must certify completion of the education to [MEDICAL BOARD(S)] no later than six months following notice of the violation.

(3)Failure to certify completion of the required education within the required time shall be considered unprofessional conduct under this chapter.