



AMERICAN SOCIETY OF
PLASTIC SURGEONS[®]

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THE PLASTIC SURGERY
FOUNDATION[™]

January 30, 2024

The Honorable Mark Sickles, *Chair*
The Honorable Kathy Tran, *Vice Chair*
House Health and Human Services Committee
1000 Bank Street
Richmond, VA 23219

Re: Recommendations for H.B. 1340

Dear Chair Sickles and Vice Chair Tran:

On behalf of the American Society of Plastic Surgeons (ASPS), I write with recommendations for House Bill 1340 (H.B. 1340). ASPS is the largest association of plastic surgeons in the world, representing more than 8,000 members and 92 percent of all board-certified plastic surgeons in the United States – including 269 board-certified plastic surgeons in Virginia. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

ASPS is pleased to be able to support the concept of this bill, as it further strengthens the systems now in place to ensure patients are fully informed prior to breast implant surgery. However, I strongly recommend certain changes to the language, and I cannot support this bill without them.

In late October of 2021, the U.S. Food and Drug Administration (FDA) mandated that breast implant manufacturers develop product-specific checklists that are approved by the FDA and, to ensure informed consent amongst patients, verify that surgeons using their devices attest to using the FDA-approved manufacturer checklist. Those checklists all follow the template provided by the FDA and contain the subject matter areas and warnings prescribed by H.B. 1340.

The objective of H.B. 1340 is important and something that ASPS supports unconditionally, and that is why plastic surgeons helped develop various iterations of breast implant patient decision checklists prior to the FDA's release of a breast implant checklist. I also strongly support the fact that H.B. 1340 further strengthens enforcement of the notification requirement by regulating medical practice, rather than just manufacturer practices. However, now that there is standardized, federally mandated language, ASPS works to ensure the support of the FDA checklist across the states. Because there is no way to circumvent the requirement that the FDA's document be used, a law creating a state-specific checklist will require the use of two largely duplicative documents during the informed consent process. Two patient checklists with substantially similar language confuses patients and adds to a dynamic that already risks information overload, and as a result totally undermines patients' ability to use the checklist process as a decision-making tool.

Fortunately, the current version of H.B. 1340 – if modified slightly – will work hand-in-hand with the FDA-mandated checklist and actually enhance the process by expanding enforcement, guaranteeing the best fit with notification requirements and ensuring there is no confusion injected into the patient communication process. I have attached an amended version of the legislation as introduced, as well with the Subcommittee’s revision, that will result in this seamless alignment.

Thank you for consideration of our comments. Please do not hesitate to contact Joe Mullin, ASPS State Affairs Manager, at jmullin@plasticsurgery.org or (847) 981-5412 with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Williams", written in a cursive style.

Steven H. Williams, MD
President, American Society of Plastic Surgeons

cc: Members, House Health and Human Services Committee

2024 SESSION

INTRODUCED

24103400D

HOUSE BILL NO. 1340

Offered January 12, 2024

A BILL to amend the Code of Virginia by adding a section numbered 54.1-2971.2, relating to Board of Medicine; breast implant patient decision checklist required.

Patron—Glass

Referred to Committee on Health and Human Services

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-2971.2 as follows:

§ 54.1-2971.2. Breast implant patient decision checklist required.

A. ~~The Board shall develop a patient decision checklist for patients considering breast implants. Such checklist shall comply with~~ enforce the U.S. Food and Drug Administration requirements for checklists distributed by breast implant manufacturers as a patient decision checklist for patients considering breast implants. ~~Such checklist shall include information on the risks of potential complications from breast implants, potential development of breast implant associated anaplastic large cell lymphoma, increased chance of development of certain autoimmune and connective tissue diseases, and other systemic symptoms associated with breast implants.~~

B. Before conducting any procedure that involves breast implants, a physician shall deliver to the patient in writing a breast implant patient decision checklist developed pursuant to subsection A and explain the information included therein. No physician shall conduct such procedure unless the patient has signed such breast implant patient decision checklist.

INTRODUCED

HB1340

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HOUSE BILL NO. 1340

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health and Human Services

on _____)

(Patron Prior to Substitute--Delegate Glass)

A BILL to direct the Board of Medicine to develop a patient decision checklist for patients considering breast implants.

Be it enacted by the General Assembly of Virginia:

1. ~~§ 1. That the Board of Medicine shall develop a patient decision checklist for patients considering breast implants. Such checklist shall comply with~~ **enforce the** U.S. Food and Drug Administration requirements for checklists distributed by breast implant manufacturers **as a patient decision checklist for patients considering breast implants.** ~~Such checklist shall include information on the risks of potential complications from breast implants, potential development of breast implant associated anaplastic large cell lymphoma, increased chance of development of certain autoimmune and connective tissue diseases, and other systemic symptoms associated with breast implants. It shall also include information about aesthetic flat closure as an alternative to breast implants.~~

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