1 INTERIM STUDY PROPOSAL 2021-103 2 REQUESTING THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND 3 4 LABOR STUDY WHETHER TO REQUIRE THAT A PATIENT PROVIDES WRITTEN 5 INFORMED CONSENT BEFORE SURGICAL MESH IMPLANTATION, WHICH 6 CONTAINS CERTAIN INFORMATION. 7 8 WHEREAS, surgical mesh is a medical device that is used to provide 9 additional support when repairing weakened or damaged tissue; and 10 WHEREAS, the majority of surgical mesh devices currently available for 11 12 use are made from man-made materials or animal tissue; and 13 14 WHEREAS, surgical mesh made of man-made materials can be found in 15 knitted mesh or nonknitted sheet forms and can either be absorbable, 16 nonabsorbable, or a combination of absorbable and nonabsorbable materials; 17 and 18 19 WHEREAS, animal-derived surgical mesh are made of animal tissue, such 20 as intestine or skin, that has been processed and disinfected to be suitable 21 for use as an implanted device; and 22 23 WHEREAS, nonabsorbable mesh will remain in the body indefinitely and is 24 considered a permanent implant, while absorbable mesh will degrade and lose 25 strength over time; and 26 27 WHEREAS, surgical mesh has been used for urogynecologic procedures, 28 including repair of pelvic organ prolapse and stress urinary incontinence; 29 and 30 31 WHEREAS, on January 5, 2016, the United States Food and Drug 32 Administration reclassified surgical mesh for transvaginal repair of pelvic organ prolapse into class III, required submission of premarket approval 33 34 applications, and mandated that premarket approval applications be filed by 35 July 5, 2018, for any surgical mesh marketed for transvaginal pelvic organ 36 prolapse repair; and

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1 2 WHEREAS, on April 16, 2019, the United States Food and Drug Administration ordered manufacturers of surgical mesh products intended for 3 4 transvaginal repair of anterior compartment prolapse to stop selling and 5 distributing their products immediately; and 6 7 WHEREAS, based on the review of available evidence, the United States 8 Food and Drug Administration believes that the benefit-risk profile of mesh 9 placed transabdominally to treat pelvic organ prolapse and mesh used to treat 10 stress urinary incontinence remains favorable; and 11 12 WHEREAS, based on the decisions of the United States Food and Drug 13 Administration, surgical mesh implantation adds another level of 14 responsibility when deciding on surgical options to repair pelvic organ 15 prolapse or stress urinary incontinence; and 16 17 WHEREAS, as surgical mesh can be a viable option for repair, the 18 informed consent process should involve a time commitment to discuss 19 thoroughly the knowns and unknowns about surgical mesh with the patient; and 20 21 WHEREAS, in order to protect the health of the citizens of this state, 22 the General Assembly should study whether to require that a patient provides 23 written informed consent before surgical mesh implantation, which contains 24 certain information, including without limitation: 25 26 (1) Information as to why the surgical mesh is being implanted; 27 (2) The United States Food and Drug Administration 28 classification of surgical mesh; and 29 (3) Complications related to surgical mesh implantation, 30 31 NOW THEREFORE, 32 BE IT PROPOSED BY THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR OF 33 THE NINETY-THIRD GENERAL ASSEMBLY: 34

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<pre>whether to require that a patient provides written informed consent before surgical mesh implantation, which contains certain information. Representation, which contains certain information. Respectfully submitted, Representative Aaron Pilkington Bistrict 69 Prepared by: JMB/JMB Prepared by: JMB</pre>	1	THAT the House Committee on Public Health, Welfare, and Labor study
4 5 6 7 8 Respectfully submitted, 9 10 11 12 Representative Aaron Pilkington 13 District 69 14 Prepared by: JMB/JMB 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 32 33 34 35	2	whether to require that a patient provides written informed consent before
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