

In the General Assembly State of \_\_\_\_\_

**“Medical Spa Safety Act.”**

**Section 1. Title.** This act shall be known as and may be cited as the “Medical Spa Safety Act.”

**Section 2. Purpose.** The legislature hereby finds and declares that:

- (a) Patients are increasingly seeking cosmetic medical procedures and it is crucial that patient safety remains the top priority for providers of these services.
- (b) These procedures are often done outside of a physician office and in a medical spa (“med spa”), many of which are legitimate, safe, physician-owned facilities that operate with a high standard of patient care.
- (c) Lack of regulation have enabled med spas to offer cosmetic medical procedures by inadequately trained or supervised persons to an unsuspecting public.
- (d) Some facilities have a physician listed as a medical director, who does not own the facility and/or is not on-site or immediately available to directly supervise non-physician providers.
- (e) It is in the public interest to protect patients from harm by ensuring that med spas deliver safe medical care supervised by an on-site physician.

**Section 3. Definitions.**

- (a) “Medical spa (med spa)” means a facility that provides cosmetic medical procedures, which may include neuromodulators, dermal fillers and non-ablative laser procedures outside of a physician’s office.

**Drafting Note – RE: “Medical spa (med spa)”:** States may choose to implement medical malpractice requirements.

- (b) “Cosmetic medical procedure” means medical procedures or treatments that are performed to alter or reshape normal structures of the body or ablate or remove living tissue solely in order to improve physical appearance.
- (c) “Medical Director” means a physician who assumes the role of, or holds oneself out as, medical director at a medical spa. The medical director is:
  - i. Trained in the indications for, and performance of, cosmetic medical procedures, including all medical devices or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue and;
  - ii. Responsible for implementing policies and procedures to ensure quality patient care and for the delegation and supervision of cosmetic medical procedures and;
  - iii. Responsible for all cosmetic medical procedures performed by physicians or non-physician providers at a medical spa and;

- 34 iv. Responsible for ensuring that all supervising physicians and non-physician  
35 providers to whom a cosmetic medical procedure has been delegated are  
36 properly trained in the safe and effective performance of all cosmetic  
37 medical procedures performed at the medical spa.

38 (d) "Physician" means an allopath or osteopath who has an active, unrestricted medical  
39 license granted under the authority of XX and practices within the state that the  
40 medical spa is located.

**Drafting Note – RE: "Physician":** States may choose to define "allopath" and "osteopath" for further clarification.

41 (e) "Delegate" means a non-physician tasked with performing a procedure as defined in  
42 Paragraph (b) by a Physician as defined in Paragraph (d).

**Drafting Note – RE: "Delegate":** States may choose to list the different types of non-physician categories that have the authority to perform cosmetic medical procedures. This should not be interpreted to expand the scope of practice authority of any non-physician health care provider.

43 (f) "Supervision" means a supervising physician that is both present at the site and  
44 immediately able to respond in-person as needed.

#### 45 **Section 4. Protecting Patients in a Medical Spa Setting**

- 46 (a) A physician who performs or supervises cosmetic medical procedures by a non-  
47 physician must be trained in the indications for and performance of the cosmetic  
48 medical procedure.
- 49 i. Training by a vendor or manufacturer of any injectables and/or medical  
50 devices used during a cosmetic medical procedure is insufficient as the  
51 physician's only educational training.
  - 52 ii. ACGME or AOA approved continuing medical education, or completion of  
53 an ACGME or AOA accredited postgraduate program that includes  
54 training in the cosmetic medical procedure being performed satisfies the  
55 education requirement.
- 56 (b) The supervising physician must:
- 57 i. Develop and maintain written office protocols for each cosmetic medical  
58 procedure.
  - 59 ii. Perform the initial assessment of the patient.
  - 60 iii. Prepare a written treatment plan for each patient, including diagnosis,  
61 course of treatment and specifications for any device being utilized.
  - 62 iv. Obtain patient consent if the procedure is being done by a non-physician  
63 provider and identify credentials and name of the non-physician provider  
64 who will be performing the medical procedure.

- 65 v. Create and maintain medical records in a manner consistent with  
66 accepted medical practice and in compliance with the rules of the State  
67 of XX.
- 68 (c) Non-physician providers may only perform cosmetic medical procedures in which  
69 they have been properly trained and if the procedure has been delegated to them  
70 by a supervising physician. All non-physician providers must:
- 71 i. Wear identification that clearly communicates they are not physicians  
72 and identifies the type of provider they are and their licensing.
- 73 ii. Review and follow written protocols for each delegated cosmetic medical  
74 procedure;
- 75 iii. Verify that the supervising physician has assessed the patient and given  
76 written treatment instructions for each procedure to be performed;
- 77 iv. Review the cosmetic medical procedure to be performed with each  
78 patient;
- 79 v. Notify the medical director and supervising physician of any adverse  
80 events or complications before the patient leaves the medical spa or as  
81 they become aware; and follow-up communications with the patient  
82 post-operatively;
- 83 vi. Document all relevant details of the cosmetic medical procedure in each  
84 patient's medical record; and
- 85 vii. Satisfy any requirements imposed by the licensing board of the non-  
86 physician.

**Drafting note - RE: Protecting Patients in a Medical Spa Setting:** This section should not be interpreted to expand existing statute or regulation regarding the scope of practice of non-physician providers.

States may choose to require medical spas to post if a physician is not on-site and mandate adverse event reporting to the U.S. Food and Drug Administration. States may also require reporting to a physician organization's adverse event database, such as the American Society for Dermatologic Surgery Association's CAPER).

**Drafting note - RE: Optional Section – Violations and Enforcement:** States should consider potential enforcement measures for non-compliance.

87 **Section 5. Effective.** This Act shall become effective immediately upon being enacted into law.