

1 **In the General Assembly State of _____**

2 **“Safe Laser and Energy-Based Device Act”**

3 **Section 1. Title.** This act shall be known as and may be cited as the “Safe Laser and Energy-
4 Based Device Act”

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

- 6 (a) As the public is increasingly seeking to undergo medical procedures that utilize
7 lasers and energy-based devices, it is paramount that the safety of patients is
8 protected.
- 9 (b) While these procedures can be extremely safe and effective when performed under
10 the proper conditions, inadequate training and supervision could lead to serious
11 unintended complications and adverse events ranging from ineffective or
12 unsatisfactory cosmetic results to permanent disfigurement.
- 13 (c) Lack of sufficient regulation and enforcement has enabled inadequately trained and
14 unsupervised persons to perform procedures on an unsuspecting public.
- 15 (d) Devices such as lasers and energy-based devices are regulated as medical devices by
16 the U.S. Food and Drug Administration and should be used only by a Physician or
17 adequately trained medical professionals under the supervision of a Physician.
- 18 (e) It is in the public interest to protect patients from potentially harmful effects by
19 restricting the use of laser and energy devices to adequately trained and supervised
20 health care professionals.

21 **Section 3. Definitions.**

- 22 (a) “Board” means the XX’s Board of Medicine.
- 23 (b) “Delegate” means a non-physician tasked with performing a procedure as defined in
24 Paragraph (c) and (d) by a Physician as defined in Paragraph (e).

Drafting Note – RE: “Delegate”: States may choose to list the different types of non-physician categories that have the authority to use lasers and energy-based devices in that state. This should not be interpreted to expand the scope of practice authority of any non-physician health care provider.

- 25 (c) “Energy-based procedure” means a medical procedure using an ultrasound,
26 cryolipolysis, microwave or radio frequency device that is not expected or intended
27 to remove, burn, or vaporize the live epidermal surface of the skin, but may damage
28 underlying tissue, if used inappropriately.

29 (d) "Laser procedure" means a medical procedure using a laser or intense pulsed light
30 device that is not expected or intended to remove, burn, or vaporize the live
31 epidermal surface of the skin, but may damage underlying tissue, if used
32 inappropriately. This definition includes procedures related to laser hair removal.

Drafting note – RE: "Definitions": A state may wish to provide alternative definitions for clarification. This drafting note recommends the following suggestion:

- (a) "Ablative procedure" means a medical procedure using a laser, ultrasound, intense pulsed light, cryolipolysis, or radio frequency device that is expected or intended to remove, burn, or vaporize live epithelium or its supporting structures, the dermis, or subcutaneous tissues, including fat. These procedures may only be performed by a physician as defined in Paragraph (e).
- (b) Nonablative procedure" means a medical procedure using a laser, ultrasound, intense pulsed light, cryolipolysis, microwave or radio frequency device that is not expected or intended to remove, burn, or vaporize the live epidermal surface of the skin, but may damage the live epidermal surface or underlying tissue if used inappropriately. This definition includes procedures related to laser hair removal.

33 (e) "Physician" means an allopath or osteopath who has an active, unrestricted medical
34 license granted under the authority of XX, practicing within the state, and whose
35 practice includes performing laser and energy based procedures and has met the
36 training requirements described in Section 7 of this act.

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

- 37 (f) "Supervision" means the overseeing of the delegated laser or energy-based
38 procedures as defined in Paragraph (c) and (d) performed by a Delegate as defined
39 in Paragraph (b). Supervision must only be provided by a Physician as defined in
40 Paragraph (e).
- 41 (g) "Surgery" is performed for the purpose of structurally altering the human body by
42 the incision or destruction of tissues and is part of the practice of medicine. Surgery
43 is also the diagnostic or therapeutic treatment of conditions or disease processes by
44 any instruments causing localized alteration or transposition of human tissue which
45 include lasers, intense pulsed light, radio frequency, focused ultrasound,
46 cryotherapy, microwave, ionizing radiation, scalpels, probes, and needles. The tissue
47 can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed
48 reductions for major dislocations or fractures, or otherwise altered by mechanical,
49 thermal, light-based, electromagnetic, or chemical means.
- 50 (h) "Written protocol" means an ongoing order that is maintained on-site at the facility
51 at which the procedure as defined in Paragraph (c) and (d) is to be performed.

52 **Section 4. General restrictions.**

- 53 (a) The use of a laser or energy-based device that is expected or intended to remove,
54 burn, or vaporize the live epidermal surface of the skin is surgery and may only be
55 performed by a Physician.
- 56 (b) A laser or energy-based procedure, including laser-assisted hair removal, may be
57 performed by a Delegate if the procedure has been delegated in accordance with
58 Section 5; the delegating Physician provides the appropriate supervision in
59 accordance with Section 6; and the Delegate has met the training requirements in
60 accordance with Section 7.

Drafting note - RE: General restrictions: This section should not be interpreted to expand existing statute or regulation regarding the scope of practice of non-physician providers.

61 **Section 5. Delegation of Laser or Energy-based Procedures.**

- 62 (a) Prior to delegating the performance of a laser or energy-based procedure, the
63 delegating Physician must perform the initial assessment of the patient to determine
64 which procedure is appropriate for the patient and determine the settings on the
65 chosen device.
- 66 (b) Prior to delegating the performance of a laser or energy-based procedure, the
67 delegating Physician must ensure that the Delegate has satisfactorily met the
68 training requirements described in Section 7 and that the procedure is within the
69 scope of practice for the Delegate's profession. The delegating Physician is
70 responsible for ensuring that the Delegate performing the procedure has
71 demonstrated sufficient proficiency for each laser and energy-based procedure
72 performed.
- 73 (c) Prior to the performance of a delegated laser or energy-based procedure, the
74 delegating Physician must inform the patient about the training and qualifications of
75 who will be performing the procedure.
- 76 (d) A Physician may delegate the performance of a laser and energy-based procedure
77 through the use of a written protocol. The written protocol must provide, at a
78 minimum:
- 79 i. the identification of the devices and settings to be used;
 - 80 ii. a description of appropriate care and follow-up for common
81 complications, injuries, or adverse reactions that may result from the
82 laser procedure, including a plan to manage medical emergencies;
 - 83 iii. a description of the treatment plan to be followed for each procedure
84 delegated under the written protocol, including the method to be used
85 for documenting decisions, communicating with the delegating Physician,
86 and recording all treatment provided in the patient's record; and

- 87 iv. a quality assurance plan for monitoring care provided by the Delegate
88 including patient care review and any necessary follow-up.
89 (e) The written protocol must be annually reviewed by the delegating Physician and the
90 Delegate and updated as necessary. The written protocol must be provided to the
91 Board or to any patient, upon request.

92 **Section 6. Supervision.**

- 93 (a) A Delegate may only perform a delegated laser or energy-based procedure under
94 the on-site supervision of a Physician. On-site supervision requires:
95 i. a Physician to be physically present in the facility where the procedure is
96 to be performed for at least the entire duration of the procedure; and
97 ii. a Physician must be immediately available and able to respond promptly
98 to any question or problem that may occur while the procedure is being
99 performed.

100 **Section 7. Training Requirements.**

- 101 (a) A Physician who delegates the performance of a laser or energy-based procedure
102 must be able to document to the Board the completion of appropriate training in
103 the physics, safety, and surgical techniques involved in the use of laser and energy-
104 based devices capable of damaging living tissues. This training should include an
105 extensive understanding of cutaneous medicine and surgery, the indications and
106 contraindications for such procedures, the pre- and post-operative care involved in
107 treatment, as well as the treatment of complications associated with these devices.
108 (b) For each laser and energy-based procedure to be performed, it is the responsibility
109 of the delegating Physician to ensure that the Delegate is appropriately trained in
110 the indications and contraindications and the pre- and post-operative care involved
111 in treatment.

Drafting note – RE: Optional Clause – Training: States may choose to require additional continuing education credit hours for non-physicians performing laser procedures. This drafting note provides the following suggestion:

(c) Delegates performing laser and energy-based procedures must complete a minimum of XX continuing education credit hours in the use of lasers and energy-related devices each biennium. This requirement is in addition to any other continuing education requirements the delegate is required to meet under the delegate’s license renewal process. The delegating Physician must ensure that the delegate has met the continuing education requirement.

112 **Section 8. Violations and Enforcement.**

- 113 (a) Failure to comply with any provision under the previous Sections shall constitute a
114 violation under this Act.

- 115 (b) Knowingly delegating a procedure using a laser, ultrasound, intense pulsed light,
116 microwave or radio frequency device other than as authorized under this act shall
117 constitute a violation under this Act.
- 118 (c) Delegating for the performance of health care services by a healthcare practitioner
119 when the Physician delegating for performance knows, or has reason to know, the
120 person does not have the required authority pursuant to the person's licensure,
121 shall constitute a violation under this Act.
- 122 (d) Each instance that this act is violated shall constitute a separate offense and shall be
123 punishable as such by the Board.

Drafting note: RE: Violations and Enforcement: States may wish to penalize a non-physician who violates the provisions of this act. This drafting note provides the following suggestion:

(d) Any Delegate who violates any provision under this Act is guilty of unprofessional conduct and subject to disciplinary action under the appropriate licensure provisions governing the respective health care practitioner.

- 124 (e) Any and all fees and other amounts billed to and paid by the patient treated under a
125 violation of this act shall be effectively rescinded and refunded.
- 126 (f) The imposition of professional sanctions, administrative fees or other disciplinary
127 actions shall be publicly reported in a journal of official record by the Board.

128 **Section 9. Effective.** This Act shall become effective immediately upon being acted into law.

Drafting note – RE: Optional Clause – Adverse Event Reporting. States may choose to require the reporting of adverse events to a state agency. The following language is recommended:

Adverse Event Reporting:

- (a) Any person utilizing a laser, ultrasound, intense pulsed light, cryolipolysis, microwave or radio frequency device shall report an adverse event no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visits, not later than 24 hours after the adverse event has been detected.*
- (b) For purposes of this section, "adverse event" includes any of the following:*
- (i.) Patient physical injury, death or serious disability. "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.*
 - (ii.) Patient physical injury, death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.*