

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) Devices such as lasers and energy-based devices are regulated as medical devices by
7 the U.S. Food and Drug Administration and should be used only by a Physician or
8 adequately trained medical professionals under the supervision of a Physician.

9 (b) It is in the public interest to protect patients from potentially harmful effects by
10 restricting the use of laser and energy devices to adequately trained and supervised
11 health care professionals.

12 **Section 3. Definitions.**

13 (a) “Board” means the XX’s Board of Medicine.

14 (b) “Physician” means an allopath or osteopath who has an active, unrestricted medical
15 license granted under the authority of XX, practicing within the state, and whose
16 practice includes performing laser and energy based procedures and has met the
17 training requirements described in Section 7 of this act.

18 (c) “Delegate” means a non-physician tasked with performing a procedure.

19 (d) “Supervision” means the overseeing of delegated laser or energy-based procedures
20 performed by a Delegate. Supervision must only be provided by a Physician as
21 defined in Paragraph (b).

22 (e) “Ablative laser procedure” means a medical procedure using a laser that is expected
23 or intended to remove, burn, or vaporize the live epidermal surface of skin.

24 (f) “Non-ablative laser procedure” means a medical procedure using a laser or intense
25 pulsed light device that is not expected or intended to remove, burn, or vaporize the
26 live epidermal surface of the skin, but may damage skin or underlying tissue if used
27 inappropriately. This definition includes procedures related to laser hair removal.

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

32

33 **Section 4. General restrictions.**

- 34 (a) The application of laser and energy-based devices to the human body is the practice
35 of medicine and surgery.
36 (b) A Physician shall not delegate ablative laser procedures.
37 (c) A Physician may delegate the application of non-ablative laser procedures and
38 energy-based procedures according to the requirements in Section 5, 6, and 7.

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

- 40 (a) Prior to delegating the performance of a laser or energy-based procedure, the
41 delegating Physician must perform the initial assessment of the patient to determine
42 which procedure is appropriate for the patient and determine the settings on the
43 chosen device.
44 (b) Prior to delegating the performance of a laser or energy-based procedure, the
45 delegating Physician must ensure that the Delegate has satisfactorily met the
46 training requirements described in Section 7 and that the procedure is within the
47 scope of practice for the Delegate's profession. The delegating Physician is
48 responsible for ensuring that the Delegate performing the procedure has
49 demonstrated sufficient proficiency for each laser and energy-based procedure
50 performed.
51 (c) Prior to the performance of a delegated laser or energy-based procedure, the
52 delegating Physician must inform the patient about the training and qualifications of
53 who will be performing the procedure.
54 (d) A Physician may delegate the performance of a laser and energy-based procedure
55 through the use of a written protocol. The written protocol must provide, at a
56 minimum:
57 i. the identification of the devices and settings to be used;
58 ii. a description of appropriate care and follow-up for common
59 complications, injuries, or adverse reactions that may result from the
60 laser procedure, including a plan to manage medical emergencies;
61 iii. a description of the treatment plan to be followed for each procedure
62 delegated under the written protocol, including the method to be used
63 for documenting decisions, communicating with the delegating Physician,
64 and recording all treatment provided in the patient's record; and
65 iv. a quality assurance plan for monitoring care provided by the Delegate
66 including patient care review and any necessary follow-up.
67 (e) The written protocol must be annually reviewed by the delegating Physician and the
68 Delegate and updated as necessary. The written protocol must be provided to the
69 Board or to any patient, upon request.

71 **Section 6. Supervision.**

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

79 **Section 7. Training Requirements.**

- 80 (a) A Physician who delegates the performance of a laser or energy-based procedure
81 must be able to document to the Board the completion of appropriate training in
82 the physics, safety, and surgical techniques involved in the use of laser and energy-
83 based devices capable of damaging living tissues. This training should include an
84 extensive understanding of cutaneous medicine and surgery, the indications and
85 contraindications for such procedures, the pre- and post-operative care involved in
86 treatment, as well as the treatment of complications associated with these devices.
- 87 (b) For each laser and energy-based procedure to be performed, it is the responsibility
88 of the delegating Physician to ensure that the Delegate is appropriately trained in
89 the indications and contraindications and the pre- and post-operative care involved
90 in treatment.

91 **Section 8. Violations and Enforcement.**

- 92 (a) Failure to comply with any provision under the previous Sections shall constitute a
93 violation under this Act.
- 94 (b) Knowingly delegating a procedure using a laser, ultrasound, cryolipolysis, intense
95 pulsed light, microwave or radio frequency device other than as authorized under
96 this act shall constitute a violation under this Act.
- 97 (c) Delegating for the performance of health care services by a healthcare practitioner
98 when the Physician delegating for performance knows, or has reason to know, the
99 person does not have the required authority pursuant to the person's licensure,
100 shall constitute a violation under this Act.
- 101 (d) Each instance that this act is violated shall constitute a separate offense and shall be
102 punishable as such by the Board.
- 103 (e) Any and all fees and other amounts billed to and paid by the patient treated under a
104 violation of this act shall be effectively rescinded and refunded.
- 105 (f) The imposition of professional sanctions, administrative fees or other disciplinary
106 actions shall be publicly reported in a journal of official record by the Board.

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