SENATE No. 01140

The Commonwealth of Massachusetts

PRESENTED BY:

Richard T. Moore

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act relative to medical spas.

PETITION OF:

NAME:DISTRICT/ADDRESS:Richard T. MooreWorcester and Norfolk

SENATE No. 01140

By Mr. Moore, petition (accompanied by bill, Senate, No. 1140) of Moore for legislation relative to medical spas [Joint Committee on Public Health].

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An Act relative to medical spas.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 111 of the General Laws as amended by Chapter 197 of the Acts
 of 2010 is hereby amended by adding the following sections: --

3 MEDICAL SPAS

4 Section 223. For the purposes of sections 223 to 228, inclusive, the following words

5 shall, unless the context clearly indicates otherwise, have the following meanings:

6 "Actively practicing," providing services or on-site supervision at the office location for a

7 majority of the weekly clinical practice time of the practitioner.

8 "Clinical director," a physician or nurse licensed under the provisions of chapter 112 who is

9 responsible for working with a site director to establish and implement policies and protocols

10 related to level II procedures at a medical spa.

11 "Commissioner," the Commissioner of Public Health.

12 "Department," the Department of Public Health.

13 "Exempt private office practice," a facility that provides medical aesthetic procedures, which is
14 wholly owned and controlled by one or more of the practitioners who actively practice at that
15 location.

16 "Laser and light-based hair removal," procedures to remove hair from the human body using

17 laser devices or other light-based devices, and which may be performed by a physician,

18 physician's assistant, nurse, electrologist or advanced aesthetician licensed to practice in

19 Massachusetts.

20 "Level I facility," any entity that provides only Level I procedures and that is licensed by either21 the board of registration of electrologists or the board of registration in cosmetology.

22 "Level I procedures," those procedures within the scope of practice of a licensed electrologist,

23 cosmetologist or aesthetician as defined by and performed under the regulatory authority and

24 jurisdiction of the board of registration of electrologists or the board of registration in

25 cosmetology.

26 "Level II procedures," those procedures defined by the commissioner in regulation, which shall27 be minimally invasive and carry minor to moderate risk to patients.

28 "Level III procedures," those procedures defined by the commissioner in regulation, which shall 29 be more invasive and of greater risk than Level II procedures, and which shall be the practice of 30 medicine or nursing. 31 "Medical aesthetic procedures," Level II and Level III procedures, as defined by the32 commissioner by regulation.

"Medical spa," any entity, however organized, whether conducted for profit or not for profit, that 33 is advertised, announced, established, or maintained for the purpose of providing medical 34 aesthetic procedures. "Medical spa" shall not include a practice wholly owned and controlled by 35 one or more practitioners if at least one of the owners is actively practicing at each office 36 location. "Medical spa" shall not include a clinic licensed pursuant to section 51 of chapter 111. 37 "Medical director," a physician licensed under the provisions of chapter 112 who is responsible 38 39 for working with a site director to establish and implement policies and protocols related to prescriptive practice and performance of medical aesthetic procedures at a medical spa licensed 40

41 to provide Level III procedures.

42 "Practitioner," a physician, physician's assistant, nurse, electrologist or advanced aesthetician43 licensed to practice in Massachusetts.

44 "Site director," a physician or nurse licensed and in good standing under the provisions of
45 chapter 112 who is employed full-time at a medical spa and responsible for the medical spa's
46 compliance with applicable laws and regulations.

47 Section 224. The department shall issue for a term of two years, and shall renew for 48 like terms, a license, subject to revocation by it for cause, to any medical spa that meets the 49 requirements of the department established in accordance with its rules and regulations; 50 provided, however, that the department shall inspect each medical spa at least once a year. The 51 department shall designate a medical spa as a Level II facility, a Level III facility or a Level II 52 and III facility, depending on the procedures that are offered.

53 Section 225. (1) No entity, however organized, whether conducted for profit or not for profit, may provide medical aesthetic services under a name that includes the words "medical 54 aesthetics," "medical spa," the word "medical" or any derivative thereof or words to similar 55 effect unless it is licensed pursuant to section 223. (2) A licensed medical spa may include a 56 Level I facility, but the Level I facility shall maintain a separate license subject to the jurisdiction 57 58 and requirements of the board of registration of electrologists or board of registration in cosmetology. (3) Each medical spa shall maintain records of each patient's visit for a minimum 59 of seven years. (4) Any practitioner who provides services in a medical spa shall have sufficient 60 61 and appropriate training, continuing education, and supervision as required by his or her licensing board. (5) Each entity that meets the definition of "medical spa" that is in operation on 62 the effective date of this act must (a) register with the department within 120 days of the 63 effective date of this act and (b) must submit an application for licensure to the department 64 within one year of the effective date of regulations promulgated by the commissioner pursuant to 65 section 226. 66

67 Section 226. (1) No person may perform a medical aesthetic procedure except to the extent authorized by his or her license issued under the provisions of chapter 112 (2) No 68 69 practitioner may perform a medical aesthetic procedure in a location that is not a licensed medical spa, an exempt private office practice, or a hospital or clinic licensed pursuant to section 70 51 of chapter 111. (3) Any practitioner who provides medical aesthetic services, whether in a 71 licensed medical spa, an exempt private office practice, or a hospital or clinic licensed pursuant 72 73 to section 51 of chapter 111 shall have sufficient and appropriate training, continuing education, and supervision as required by his or her licensing board. This section shall not apply to students 74

enrolled in professional schools for professions permitted to perform medical aestheticprocedures as part of their training.

77 Section 227. A medical spa licensed to provide level II procedures shall have a clinical director and a site director, which may be the same person. The clinical director shall have 78 79 sufficient and appropriate training, as the department shall define by regulation, to perform and supervise any Level II procedures performed in the medical spa. The clinical director shall be 80 81 physically present in the medical spa for a period of time equal to at least ten percent of the hours of operation of the medical spa each month and shall be available to all staff for consultation and 82 referral as needed. The clinical director or another experienced nurse or physician with 83 84 appropriate training shall perform all patient assessments for level II procedures and shall make 85 appropriate referrals to a collaborating physician as necessary. The site director shall have 86 clinical training and experience that is sufficient to perform and supervise the performance of any Level II procedures performed in a medical spa for which he or she serves as site director. 87 The site director shall be responsible for a site-based credentialing process for all licensed 88 professionals in the medical spa that includes requirements related to professional licensure, 89 training, continuing education, and experience, and for ensuring that all licensed professionals in 90 91 the medical spa have adequate back-up coverage as needed. Each site director must be physically present in the medical spa during the hours of operation of the medical spa or shall 92 designate an equally qualified substitute if he or she is unable to be present in a medical spa at 93 any particular time. 94

95 Section 228. A medical spa licensed to provide level III procedures shall have a
96 medical director and a site director, which may be the same person. The medical director shall
97 have sufficient and appropriate training, as the department shall define by regulation, to perform

98 and supervise any Level III procedures performed in the medical spa. The medical director shall 99 be physically present in the medical spa for a period of time equal to at least ten percent of the 100 hours of operation of the medical spa each month and shall be available to all staff for consultation and referral as needed. The site director shall have clinical training and experience 101 that is sufficient to perform and supervise the performance of any Level III procedures 102 103 performed in a medical spa for which he or she serves as site director. The site director shall be responsible for a site-based credentialing process for all licensed professionals in the medical spa 104 that includes requirements related to professional licensure, training, continuing education, and 105 106 experience, and for ensuring that all licensed professionals in the medical spa have adequate back-up coverage as needed. Each site director must be physically present in the medical spa 107 during the hours of operation of the medical spa or shall designate an equally qualified substitute 108 109 if he or she is unable to be present in a medical spa at any particular time.

110 Section 229. The commissioner shall promulgate rules and regulations to implement 111 the provisions of sections 223-228. Notwithstanding any general or special law to the contrary, the commissioner shall not be required to receive the approval of the public health council prior 112 to promulgation of such regulations. The regulations shall incorporate to the extent possible the 113 recommendations of the medical spa task force created pursuant to St. 2006, c. 81 and shall 114 115 include but not be limited to, a list of medical aesthetic procedures, classified as Level II and Level III procedures, that may be performed in medical spas; the appropriate levels of training 116 for practitioners in medical spas; the requirements and duties of a medical spa medical director; 117 118 the requirements and duties of a medical spa site director; the appropriate levels of supervision required in medical spas; evidence of responsibility and suitability to operate a medical spa; 119 retention of records; emergency procedures; staffing requirements; sale of goods within a 120

121 medical spa, and physical plant requirements. Nothing in this section shall be construed to grant 122 authority to the commissioner to limit or diminish the authority or jurisdiction of a licensing 123 board under the provisions of chapter 112 to define the scope of practice for its licensees or 124 investigate or discipline a licensee practicing under the provisions of this section.

125 Section 230. There shall be a medical spa advisory committee, composed of one representative each from the boards of registration in medicine, nursing, electrology and 126 cosmetology appointed by each board's executive director, one representative from the 127 128 department appointed by the commissioner, one physician appointed by the board of registration in medicine, one nurse appointed by the board of registration in nursing, one electrologist 129 130 appointed by the board of registration of electrologists, one licensed cosmetologist appointed by 131 the board of registration in cosmetology, one advanced aesthetician appointed by the board of 132 registration in cosmetology, one representative from a medical equipment manufacturer 133 appointed by the department, and one owner of a medical spa licensed by the department, and appointed by the department. The commissioner shall appoint one member as chairman. The 134 members shall serve staggered three-year terms. At the end of each member's term, he or she 135 136 may continue to serve until his or her successor is appointed and qualified. The committee shall meet as frequently as the chairman deems necessary, but not less than once each year. The 137 138 committee shall advise the commissioner on the appropriate classification of new medical 139 aesthetic procedures and technologies, and on other matters pertaining to the appropriate regulation of medical spas. The committee shall also have the right to review and comment upon 140141 all rules, regulations and guidelines issued by the commissioner at least 60 days before the date such rules, regulations or guidelines become final, but in the case of emergency regulations the 142 time period shall be a reasonable time under the circumstances. The committee may also make 143

recommendations as to matters concerning medical aesthetic procedures to the board of
registration in medicine, the board of registration in nursing, the board of registration of
electrologists or the board of registration in cosmetology and may periodically advise the joint
committee on public health care on actions, including legislation, that may improve the quality of
medical aesthetics or medical spas.

149 Section 231. Any person who operates an unlicensed medical spa shall for a first offense be punished by a fine of not more than five hundred dollars, and for a subsequent offense 150 151 by a fine of not more than one thousand dollars or by imprisonment for not more than two years. A separate and distinct offense shall be deemed to have been committed on every day during 152 153 which any violation continues after written notice thereof by the department. The commissioner 154 shall report to the attorney general any violation of section 224. Any fines collected pursuant to 155 this provision shall be deposited into the account established by the Department for the 156 regulation of medical spas.

157 Section 232. Whenever the department finds upon inspection, or through information in its possession, that any licensed medical spa is not in compliance with a requirement 158 159 established under sections 223-228 or the regulations promulgated thereunder, the department may order the licensee to correct such deficiency. Every such correction order shall include a 160 161 statement of the deficiencies found, the period prescribed within which the deficiency must be corrected, and the provisions of law relied upon. The department may assess the person ordered 162 163 to correct deficiencies no less than \$1,000 and not more than \$10,000 per deficiency for each day the deficiency continues to exist beyond the date prescribed for correction. Within seven days of 164 165 receipt, the affected person may file a written request with the department for administrative 166 reconsideration of the order or any portion thereof. Any fines collected pursuant to this

provision shall be deposited into the account established by the Department for the regulation ofmedical spas.

169 SECTION 2. Section 87EEE of chapter 112 of the General Laws as appearing in the
170 2008 Official Edition is hereby amended as follows:

171 For the purposes of sections eighty-seven FFF to eighty-seven OOO, inclusive, the following
172 words shall, unless the context requires otherwise, have the following meanings:—

173 "Board", the board of registration of electrologists established under section fifty-eight of174 chapter thirteen.

"Electrolysis", the method of removing hair from the human body by the application of an
electrical or radiofrequency current to the hair-papilla by means of a needle or any other
instrument or device to cause decomposition, coagulation or dehydration of the hair-papilla and
thus permanently remove the hair. Said definition shall also include, but not limit other licensed
professions from performing, the removal of hair from the human body by use of lasers or
intense pulse light devices.

181 SECTION 3. Chapter 112 of the General Laws as appearing in the 2008 Official
182 Edition is hereby amended by inserting after section 87GGG the following section:

Section 87GGG ¹/₂. A licensed electrologist who was licensed prior to the inclusion of laser or intense pulse light devices in the educational curriculum shall not be allowed to use said devices prior to meeting educational and examination requirements as established by the Board. The use of said devices by a licensed electrologist who has not met the Board requirements shall be deemed practice outside the scope of the license issued to that individual, unprofessional conduct pursuant to G.L. c. 112, §87III; such uses may thus subject the licensee to disciplinary action asdetermined by the Board.

SECTION 4. Chapter 112 of the general laws as so appearing is hereby further
amended by inserting after section 87DD the following section: --

Section 87DD1/2. A medical spa licensed pursuant to section 224 of chapter 111, an exempt private office practice of a physician, or a hospital or clinic licensed pursuant to section 51 of chapter 111 shall not be deemed to be an aesthetic shop for the purposes of section 87DD of chapter 112 nor shall the board of registration in cosmetology have any jurisdiction over the physical premises of a medical spa licensed pursuant to section 224 of chapter 111, an exempt private office practice of a physician, or a hospital or clinic licensed pursuant to section 51.

SECTION 5. Said chapter 112 of the general laws as amended by Chapter 322 of the
Acts of 2010 is hereby further amended by adding at the end thereof the following section:-

Section 263. Nothing in this chapter shall limit the ability of employees or authorized
representatives of a manufacturer of a device used for medical aesthetic procedures from
engaging in one or more of the following: demonstrating, evaluating, adjusting, measuring,
designing, fabricating, assembling, fitting, servicing, training, repairing, replacing, or delivering
a device used to provide medical aesthetic procedures.

SECTION 6. Notwithstanding the provisions of section 87GGG 1/2 of chapter 112 of the General Laws, for a period of one year after the effective date of said section, a licensed individual shall not be required to obtain additional education to qualify to take an examination to allow the use of laser and intense pulse light devices if he or she can demonstrate to the Board that he or she has had training and actual experience in the use of laser and intense pulse light

- 210 devices. Such training and experience shall only be credited if the Board determines, in its
- 211 discretion, that the licensee has adequate knowledge to safely and effectively utilize laser and
- 212 intense pulse light devices.