

SENATE No. 1140

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 adoption of the accompanying bill:

An Act relative to medical spas.

PETITION OF:

NAME:

Richard T. Moore

DISTRICT/ADDRESS:

SENATE No. 1140

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:

1 SECTION 1. Chapter 111 of the General Laws as amended by Chapter 197 of
2 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
5 words 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
9 is 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,
14 which is wholly owned and controlled by one or more of the practitioners who actively practice
15 at that location.

16 “Laser and light-based hair removal,” procedures to remove hair from the human body
17 using 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
21 either 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
23 electrologist, cosmetologist or aesthetician as defined by and performed under the regulatory
24 authority and jurisdiction of the board of registration of electrologists or the board of registration
25 in cosmetology.

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

28 “Level III procedures,” those procedures defined by the commissioner in regulation,
29 which shall be more invasive and of greater risk than Level II procedures, and which shall be the
30 practice of medicine or nursing.

31 “Medical aesthetic procedures,” Level II and Level III procedures, as defined by the
32 commissioner by regulation.

“Medical spa,” any entity, however organized, whether conducted for profit or not for profit, that is advertised, announced, established, or maintained for the purpose of providing medical aesthetic procedures. “Medical spa” shall not include a practice wholly owned and controlled by one or more practitioners if at least one of the owners is actively practicing at each office location. “Medical spa” shall not include a clinic licensed pursuant to section 51 of chapter 111.

“Medical director,” a physician licensed under the provisions of chapter 112 who is responsible 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 to provide Level III procedures.

“Practitioner,” a physician, physician’s assistant, nurse, electrologist or advanced aesthetician licensed to practice in Massachusetts.

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

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

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

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

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

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 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 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 referral as needed. The clinical director or another experienced nurse or physician with appropriate training shall perform all patient assessments for level II procedures and shall make appropriate referrals to a collaborating physician as necessary. The site director shall have 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. The site director shall be responsible for a site-based credentialing process for all licensed professionals in the medical spa that includes requirements related to professional licensure, training, continuing education, and 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 during the hours of operation of the medical spa or shall designate an equally qualified substitute if he or she is unable to be present in a medical spa at any particular time.

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

and supervise any Level III procedures performed in the medical spa. The medical director shall be 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 referral as needed. The site director shall have clinical training and experience that is sufficient to perform and supervise the performance of any Level III procedures 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 that includes requirements related to professional licensure, training, continuing education, and 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 during the hours of operation of the medical spa or shall designate an equally qualified substitute if he or she is unable to be present in a medical spa at any particular time.

Section 229. The commissioner shall promulgate rules and regulations to implement 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 to promulgation of such regulations. The regulations shall incorporate to the extent possible the recommendations of the medical spa task force created pursuant to St. 2006, c. 81 and shall 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 for practitioners in medical spas; the requirements and duties of a medical spa medical director; 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; retention of records; emergency procedures; staffing requirements; sale of goods

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

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

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.

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 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 which any violation continues after written notice thereof by the department. The commissioner shall report to the attorney general any violation of section 224. Any fines collected pursuant to this provision shall be deposited into the account established by the Department for the regulation of medical spas.

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 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 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 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 receipt, the affected person may file a written request with the department for administrative 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 of medical spas.

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

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

“Board”, the board of registration of electrologists established under section fifty-eight of 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.

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

Section 87GGG ½. 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 as determined 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

211 to the Board that he or she has had training and actual experience in the use of laser and intense
212 pulse light devices. Such training and experience shall only be credited if the Board determines,
213 in its discretion, that the licensee has adequate knowledge to safely and effectively utilize laser
214 and intense pulse light devices.