2021 -- H 5844 SUBSTITUTE A

LC002146/SUB A/2

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2021

AN ACT

RELATING TO HEALTH AND SAFETY

Introduced By: Representatives Baginski, Casimiro, and Bennett

<u>Date Introduced:</u> February 24, 2021

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

1	SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby
2	amended by adding thereto the following chapter:
3	CHAPTER 95
4	MEDICAL SPAS
5	23-95-1. Definitions.
6	For purposes of this chapter:
7	(1) "Ablative lasers or ablative energy devices" means lasers intended to excise or vaporize
8	the outer layer of skin.
9	(2) "Advanced Practice Registered Nurse" or "APRN" means a registered nurse who has
10	an active, unrestricted advanced practice registered nurse license granted under the authority of
11	chapter 34 of title 5.
12	(3) "Cosmetic medical procedure" means any procedure that does not require sedation that
13	is performed on a person and is directed at improving the person's appearance and does not
14	meaningfully promote the proper function of the body or prevent or treat illness or disease.
15	Cosmetic medical procedures may include, but are not limited to, cosmetic surgery, microneedling,
16	hair transplants, cosmetic injections, cosmetic soft tissue fillers, dermaplaning, dermastamping,
17	dermarolling, dermabrasion that removes cells beyond the stratum corneum, chemical peels using
18	modification solutions that exceed thirty percent (30%) concentration with a pH value of lower
19	than 3.0, laser hair removal, laser skin resurfacing, laser treatment of leg veins, sclerotherapy and

1	other laser procedures, intense pulsed light, injection of cosmetic filling agents and neurotoxins and
2	the use of class II medical devices designed to induce deep skin tissue alteration. The performance
3	of cosmetic medical services is the practice of medicine and surgery. A cosmetic medical service
4	shall be performed only by a qualified licensed or certified non-physician if the services have been
5	delegated by a medical director, supervising physician, or APRN who is responsible for on-site
6	supervision of the services performed.
7	(4) "Delegate" means a non-physician tasked with performing a procedure as defined § 23-
8	95-1(3) by a physician or APRN.
9	(5) "Department" means the Rhode Island department of health.
10	(6) "Medical director" means a physician who assumes the role of, or holds oneself out as,
11	medical director at a medical spa. The medical director shall be:
12	(i) Trained in the indications for, and performance of, cosmetic medical procedures,
13	including all medical devices or instruments that can alter or cause biological change or damage
14	the skin and subcutaneous tissue. Training programs provided by a manufacturer or vendor of a
15	medical device or supplies may not be a medical director's, supervising physician's or APRN's only
16	education in the cosmetic medical service or the operation of medical devices to be used;
17	(ii) Responsible for implementing policies and procedures to ensure quality patient care;
18	(iii) Responsible for the delegation and supervision of cosmetic procedures;
19	(iv) Responsible for the oversight of all cosmetic medical procedures performed by
20	physicians, APRNs, and non-physicians; and
21	(v) Responsible for ensuring that all supervising physicians and supervising APRNs, any
22	physicians and APRNs performing cosmetic medical procedures, and any non-physicians and non-
23	APRNs delegated to perform cosmetic medical procedures, are properly trained in the safe and
24	effective performance of all cosmetic medical procedures that they perform at the medical spa.
25	(7) "Medical spa" means an establishment in which cosmetic medical procedures are
26	performed.
27	(8) "Physician" means an allopath or osteopath who has an active license, unrestricted
28	medical license granted under the authority of chapter 37 of title 5.
29	(9) "Supervision" means an arrangement when a qualified supervising physician or APRN
30	is either:
31	(i) On site and able to directly observe the treatment being performed, though not
32	necessarily in the same room (i.e., direct supervision); or
33	(ii) Is off site, but immediately available if needed, either in person or by
34	telecommunication (i.e., indirect supervision).

1	23-95-2. Protection of patients in a medical spa.
2	(a) A physician or APRN who performs cosmetic medical procedures, or supervises such
3	procedures delegated to and performed by a non-physician or non-APRN, must be trained in the
4	indications for and performance of the cosmetic medical procedure. An APRN who performs
5	cosmetic medical procedures, or supervises such procedures delegated to and performed by a non-
6	physician or non-APRN, must be accredited by the state board of nursing.
7	(b) The supervising physician or APRN shall:
8	(1) Develop and maintain written office protocols for each cosmetic medical procedure.
9	Such protocols shall be kept on site at the medical spa for review and/or inspection by the
10	department.
11	(2) Perform an initial assessment of the patient.
12	(3) Prepare a written treatment plan for each patient, which plan shall include, as
13	applicable, diagnoses, course of treatment, and specifications for any device being used.
14	(4) Obtain patient consent, if the cosmetic medical procedure(s) are being performed by a
15	non-physician or non-APRN and documenting, in the patient's medical record, the credentials and
16	names of the non-physician or non-APRN who will be performing the cosmetic medical procedure.
17	(5) Create and maintain medical records in a manner consistent with applicable laws and
18	regulations and accepted medical practice.
19	(c) Non-physicians and non-APRNs may only perform cosmetic medical procedures:
20	(1) For which they have the requisite training; and
21	(2) Which have been delegated to them by a supervising physician or APRN.
22	(d) At all times in the performance of their duties relative to cosmetic procedures, all
23	non-physicians and non-APRNs shall:
24	(1) Wear identification that identifies them as not being physicians or APRNs. As
25	applicable, such identification must identify the non-physician/non-APRN's job title and
26	credentials, including professional license;
27	(2) Review and follow written protocols for each delegated cosmetic medical procedure;
28	(3) Verify that the supervising physician or supervising APRN has assessed the patient and
29	given written treatment instructions for each procedure performed;
30	(4) Review the cosmetic medical procedure with each patient;
31	(5) Notify the medical director, as well as the supervising physician or supervising APRN,
32	before the patient leaves or as they become aware, of any adverse events or complications, and
33	follow up with the patient post-procedure, as appropriate;
34	(6) Document all relevant details of the performed cosmetic medical procedure in the

1	patient's medical record; and
2	(7) As applicable, satisfy any requirements imposed upon them by their licensing boards.
3	(e) Cosmetic medical procedures using ablative lasers or ablative energy devices shall only
4	be performed by physicians.
5	23-95-3. Rules and regulations.
6	The department shall, by July 1, 2022, promulgate rules and regulations necessary and not
7	inconsistent with law to implement the purpose and intent of this chapter, which rules and
8	regulations shall provide for, though not be limited to, the licensing of medical spas as health care
9	<u>facilities.</u>
10	SECTION 2. Section 23-17-2 of the General Laws in Chapter 23-17 entitled "Licensing of
11	Healthcare Facilities" is hereby amended to read as follows:
12	23-17-2. Definitions.
13	As used in this chapter:
14	(1) "Affiliate" means a legal entity that is in control of, is controlled by, or is in common
15	control with another legal entity.
16	(2) "Alzheimer's dementia special-care unit or program" means a distinct living
17	environment within a nursing facility that has been physically adapted to accommodate the
18	particular needs and behaviors of those with dementia. The unit provides increased staffing;
19	therapeutic activities designed specifically for those with dementia; and trains its staff on an
20	ongoing basis on the effective management of the physical and behavioral problems of those with
21	dementia. The residents of the unit/program have had a standard, medical-diagnostic evaluation
22	and have been determined to have a diagnosis of Alzheimer's dementia or another dementia.
23	(3)(i) "Change in operator" means a transfer by the governing body or operator of a
24	healthcare facility to any other person (excluding delegations of authority to the medical or
25	administrative staff of the facility) of the governing body's authority to:
26	(A) Hire or fire the chief executive officer of the healthcare facility;
27	(B) Maintain and control the books and records of the healthcare facility;
28	(C) Dispose of assets and incur liabilities on behalf of the healthcare facility; or
29	(D) Adopt and enforce policies regarding operation of the healthcare facility.
30	(ii) This definition is not applicable to circumstances wherein the governing body of a
31	healthcare facility retains the immediate authority and jurisdiction over the activities enumerated
32	in subdivisions $(3)(i)(A) (3)(i)(D)$.
33	(4) "Change in owner" means:
34	(i) In the case of a healthcare facility that is a partnership, the removal, addition, or

- substitution of a partner that results in a new partner acquiring a controlling interest in the partnership;
- 3 (ii) In the case of a healthcare facility that is an unincorporated, solo proprietorship, the 4 transfer of the title and property to another person;
 - (iii) In the case of a healthcare facility that is a corporation:
- 6 (A) A sale, lease exchange, or other disposition of all, or substantially all, of the property
 7 and assets of the corporation; or
- 8 (B) A merger of the corporation into another corporation; or

- (C) The consolidation or two (2) or more corporations, resulting in the creation of a new corporation; or
- (D) In the case of a healthcare facility that is a business corporation, any transfer of corporate stock that results in a new person acquiring a controlling interest in the corporation; or
- (E) In the case of a healthcare facility that is a nonbusiness corporation, any change in membership that results in a new person acquiring a controlling vote in the corporation.
- (5) "Clinician" means a physician licensed under chapter 37 of title 5; a nurse licensed under chapter 34 of title 5; a psychologist licensed under chapter 44 of title 5; a social worker licensed under chapter 39.1 of title 5; a physical therapist licensed under chapter 40 of title 5; and a speech language pathologist or audiologist licensed under chapter 48 of title 5.
 - (6) "Director" means the director of the Rhode Island state department of health.
- (7) "Freestanding emergency-care facility" means an establishment, place, or facility that may be a public or private organization, structurally distinct and separate from a hospital; staffed, equipped, and operated to provide prompt, emergency medical care. For the purposes of this chapter, "emergency medical care" means services provided for a medical condition or behavioral-health condition that is manifested by symptoms of sufficient severity that, in the absence of immediate medical attention, could result in harm to the person or others; serious impairment to bodily functions; serious dysfunction of any bodily organ or part; or development or continuance of severe pain.
- (8) "Healthcare facility" means any institutional health-service provider, facility, or institution, place, building, agency, or portion thereof, whether a partnership or corporation, whether public or private, whether organized for profit or not, used, operated, or engaged in providing healthcare services, including, but not limited to: hospitals; nursing facilities; home nursing-care provider (which shall include skilled nursing services and may also include activities allowed as a home-care provider or as a nursing service agency); home-care provider (which may include services such as personal care or homemaker services); rehabilitation centers; kidney

disease treatment centers; health maintenance organizations; freestanding emergency-care facilities as defined in this section, and facilities providing surgical treatment to patients not requiring hospitalization (surgi-centers); hospice care, and physician ambulatory-surgery centers and podiatry ambulatory-surgery centers providing surgical treatment. The term "health-care facility" also includes organized ambulatory-care facilities that are not part of a hospital but that are organized and operated to provide healthcare services to outpatients, such as: central-services facilities serving more than one healthcare facility or healthcare provider; treatment centers; diagnostic centers; outpatient clinics; medical spas as defined in chapter 95 of title 23; infirmaries and health centers; school-based health centers, and neighborhood health centers. The term "healthcare facility" also includes a mobile, health-screening vehicle as defined in this section. The term "healthcare facility" shall not apply to organized, ambulatory-care facilities owned and operated by professional service corporations as defined in chapter 5.1 of title 7, as amended (the "professional service corporation law"), or to a practitioner's (physician, dentist, or other healthcare provider) office or group of practitioners' offices (whether owned and/or operated by a hospital or an affiliate of a hospital or an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association); provided, however, notwithstanding any other provision herein or in the general laws, any hospital or any affiliate of a hospital that owns and/or operates a practitioner's office shall ensure that such practitioner's office complies with licensing or accreditation requirements that may be applicable to the practitioner's office. Individual categories of healthcare facilities shall be defined in rules and regulations promulgated by the licensing agency with the advice of the health services council. Rules and regulations concerning hospice care shall be promulgated with regard to the "Standards of a Hospice Program of Care," promulgated by the National Hospice Organization. Any provider of hospice care who provides hospice care without charge shall be exempt from the licensing provisions of this chapter but shall meet the "Standards of a Hospice Program of Care." Facilities licensed by the department of behavioral healthcare, developmental disabilities and hospitals and the department of human services, and clinical laboratories licensed in accordance with chapter 16.2 of this title, as well as Christian Science institutions (also known as Christian Science Nursing Facilities) listed and certified Commission Accreditation of Christian by the for Science Organizations/Facilities, Inc. shall not be considered health-care facilities for purposes of this chapter. (9) "Homemaker," or however else called, means a trained, non-professional worker who

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- (10) "Hospital" means a person or governmental entity licensed in accordance with this chapter to establish, maintain, and operate a hospital.
- (11) "Licensing agency" means the Rhode Island state department of health.

- 4 (12) "Medical services" means any professional services and supplies rendered by, or under 5 the direction of, persons duly licensed under the laws of this state to practice medicine, surgery, or 6 podiatry that may be specified by any medical service plan. Medical service shall not be construed 7 to include hospital services.
- 8 (13) "Mobile, health-screening vehicle" means a mobile vehicle, van, or trailer that delivers 9 primary and preventive healthcare screening services, and:
 - (i) Does not maintain active contracts or arrangements with any health insurer subject to regulation under chapter 20 or 42 of title 27;
 - (ii) Does not maintain active contracts or arrangements with another licensed healthcare facility as that term is defined within this section; and
 - (iii) Does not provide medical services free of charge.
 - (14) "Non-English speaker" means a person who cannot speak or understand, or has difficulty in speaking or understanding, the English language, because he/she uses only, or primarily, a spoken language other than English, and/or a person who uses a sign language and requires the use of a sign-language interpreter to facilitate communication.
 - (15) "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies, and insurance companies), state, or political subdivision or instrumentality of a state.
 - (16) "Physician ambulatory-surgery center" means an office, or portion of an office, that is utilized for the purpose of furnishing surgical services to the owner and/or operator's own patients on an ambulatory basis, and shall include both single-practice, physician ambulatory-surgery centers and multi-practice, physician ambulatory-surgery centers. A "single-practice, physician ambulatory-surgery center" is a physician ambulatory center owned and/or operated by a physician-controlled professional service corporation as defined in chapter 5.1 of title 7 (the "professional service corporation law"), or a physician-controlled limited-liability company (as defined in chapter 16 of title 7 (the "limited liability company act")) in which no physician is an officer, shareholder, director, or employee of any other corporation engaged in the practice of the same profession, or a private physician's office (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, limited-liability company, organization, or association). A "multi-practice, physician ambulatory-surgery center" is a physician ambulatory-surgery center owned and/or operated by a physician-controlled professional

service corporation (as defined in the professional service corporation law) or a physician-controlled limited-liability company (as defined in the limited liability company act) in which a physician is also an officer, shareholder, director, or employee of another corporation engaged in the practice of the same profession, or a group of physicians' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, limited-liability company, organization, or association).

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- (17) "Podiatry ambulatory-surgery center" means an office or portion of an office that is utilized for the purpose of furnishing surgical services to the owner and/or operator's own patients on an ambulatory basis, and shall include both single-practice, podiatry ambulatory-surgery centers and multi-practice podiatry ambulatory-surgery centers. A "single-practice podiatry ambulatorysurgery center" is a podiatry ambulatory center owned and/or operated by a podiatrist-controlled professional service corporation (as defined in chapter 5.1 of title 7 (the "professional service corporation law")), or a podiatrist-controlled limited-liability company (as defined in chapter 16 of title 7 (the "limited liability company act")) in which no podiatrist is an officer, shareholder, director, or employee of any other corporation engaged in the practice of the same profession, or a private podiatrist's office (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, limited-liability company, organization, or association). A "multi-practice, podiatry ambulatory-surgery center" is a podiatry ambulatory-surgery center owned and/or operated by a podiatry-controlled professional service corporation (as defined in the professional service corporation law) or a podiatry-controlled, limited-liability company (as defined in the limited liability company act) in which a podiatrist is also an officer, shareholder, director, or employee of another corporation engaged in the practice of the same profession, or a group of podiatrists' offices (whether owned and/or operated by a an individual practitioner, alone or as a member of a partnership, professional service corporation, limited-liability company, organization, or association).
- (18) "Qualified interpreter" means a person who, through experience and/or training, is able to translate a particular foreign language into English, with the exception of sign-language interpreters who must be licensed in accordance with chapter 71 of title 5.
- (19) "Qualified sign-language interpreter" means one who has been licensed in accordance with the provisions of chapter 71 of title 5.
- 31 (20) "School-based health center" means a facility located in an elementary or secondary 32 school that delivers primary and preventive healthcare services to students on site.
- 33 SECTION 3. Section 23-15-2 of the General Laws in Chapter 23-15 entitled 34 "Determination of Need for New Healthcare Equipment and New Institutional Health Services" is

hereby amended to read as follows:

23-15-2. Definitions.

3 As used in this chapter:

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- (1) "Affected person" means and includes the person whose proposal is being reviewed, or the applicant, healthcare facilities located within the state that provide institutional health services, the state medical society, the state osteopathic society, those voluntary nonprofit area-wide planning agencies that may be established in the state, the state budget office, the office of health insurance commissioner, any hospital or medical-service corporation organized under the laws of the state, the statewide health coordinating council, contiguous health-systems agencies, and those members of the public who are to be served by the proposed, new institutional health services or new healthcare equipment.
- (2) "Cost-impact analysis" means a written analysis of the effect that a proposal to offer or develop new institutional health services or new healthcare equipment, if approved, will have on healthcare costs and shall include any detail that may be prescribed by the state agency in rules and regulations.
 - (3) "Director" means the director of the Rhode Island state department of health.
- (4)(i) "Healthcare facility" means any institutional health-service provider, facility or institution, place, building, agency, or portion of them, whether a partnership or corporation, whether public or private, whether organized for profit or not, used, operated, or engaged in providing healthcare services that are limited to hospitals, nursing facilities, home nursing-care provider, home-care provider, hospice provider, inpatient rehabilitation centers (including drug and/or alcohol abuse treatment centers), freestanding emergency-care facilities as defined in § 23-17-2, certain facilities providing surgical treatment to patients not requiring hospitalization (surgicenters, multi-practice, physician ambulatory-surgery centers and multi-practice, podiatry ambulatory-surgery centers) and facilities providing inpatient hospice care. Single-practice physician or podiatry ambulatory-surgery centers (as defined in subdivisions 23-17-2(16) and 23-17-2(17), respectively) are exempt from the requirements of chapter 15 of this title; provided, however, that such exemption shall not apply if a single-practice physician or podiatry ambulatorysurgery center is established by a medical practice group (as defined in § 5-37-1) within two (2) years following the formation of such medical practice group, when such medical practice group is formed by the merger or consolidation of two (2) or more medical practice groups or the acquisition of one medical practice group by another medical practice group. Medical spas as defined in chapter 95 of title 23 are exempt from the requirements of chapter 15 of this title. The term "healthcare facility" does not include Christian Science institutions (also known as Christian

- Science nursing facilities) listed and certified by the Commission for Accreditation of Christian

 Science Nursing Organizations/Facilities, Inc.
- 3 (ii) Any provider of hospice care who provides hospice care without charge shall be exempt
 4 from the provisions of this chapter.

- (5) "Healthcare provider" means a person who is a direct provider of healthcare services (including but not limited to physicians, dentists, nurses, podiatrists, physician assistants, or nurse practitioners) in that the person's primary current activity is the provision of healthcare services for persons.
- (6) "Health services" means organized program components for preventive, assessment, maintenance, diagnostic, treatment, and rehabilitative services provided in a healthcare facility.
- (7) "Health services council" means the advisory body to the Rhode Island state department of health established in accordance with chapter 17 of this title, appointed and empowered as provided to serve as the advisory body to the state agency in its review functions under this chapter.
- (8) "Institutional health services" means health services provided in or through healthcare facilities and includes the entities in or through that the services are provided.
- (9) "New healthcare equipment" means any single piece of medical equipment (and any components that constitute operational components of the piece of medical equipment) proposed to be utilized in conjunction with the provision of services to patients or the public, the capital costs of which would exceed two million two hundred fifty thousand dollars (\$2,250,000); provided, however, that the state agency shall exempt from review any application that proposes one-for-one equipment replacement as defined in regulation. Further, beginning July 1, 2012, and each July thereafter, the amount shall be adjusted by the percentage of increase in the consumer price index for all urban consumers (CPI-U) as published by the United States Department of Labor Statistics as of September 30 of the prior calendar year.
 - (10) "New institutional health services" means and includes:
- 26 (i) Construction, development, or other establishment of a new healthcare facility.
 - (ii) Any expenditure, except acquisitions of an existing healthcare facility, that will not result in a change in the services or bed capacity of the healthcare facility by, or on behalf of, an existing healthcare facility in excess of five million two hundred fifty thousand dollars (\$5,250,000) which is a capital expenditure including expenditures for predevelopment activities; provided further, beginning July 1, 2012, and each July thereafter, the amount shall be adjusted by the percentage of increase in the consumer price index for all urban consumers (CPI-U) as published by the United States Department of Labor Statistics as of September 30 of the prior calendar year.
 - (iii) Where a person makes an acquisition by, or on behalf of, a healthcare facility or health

maintenance organization under lease or comparable arrangement or through donation, which would have required review if the acquisition had been by purchase, the acquisition shall be deemed a capital expenditure subject to review.

- (iv) Any capital expenditure that results in the addition of a health service or that changes the bed capacity of a healthcare facility with respect to which the expenditure is made, except that the state agency may exempt from review, by rules and regulations promulgated for this chapter, any bed reclassifications made to licensed nursing facilities and annual increases in licensed bed capacities of nursing facilities that do not exceed the greater of ten (10) beds or ten percent (10%) of facility licensed bed capacity and for which the related capital expenditure does not exceed two million dollars (\$2,000,000).
- (v) Any health service proposed to be offered to patients or the public by a healthcare facility that was not offered on a regular basis in or through the facility within the twelve-month (12) period prior to the time the service would be offered, and that increases operating expenses by more than one million five hundred thousand dollars (\$1,500,000), except that the state agency may exempt from review, by rules and regulations promulgated for this chapter, any health service involving reclassification of bed capacity made to licensed nursing facilities. Further, beginning July 1, 2012, and each July thereafter, the amount shall be adjusted by the percentage of increase in the consumer price index for all urban consumers (CPI-U) as published by the United States Department of Labor Statistics as of September 30 of the prior calendar year.
- (vi) Any new or expanded tertiary or specialty-care service, regardless of capital expense or operating expense, as defined by and listed in regulation, the list not to exceed a total of twelve (12) categories of services at any one time and shall include full-body magnetic resonance imaging and computerized axial tomography; provided, however, that the state agency shall exempt from review any application that proposes one-for-one equipment replacement as defined by and listed in regulation. Acquisition of full body magnetic resonance imaging and computerized axial tomography shall not require a certificate-of-need review and approval by the state agency if satisfactory evidence is provided to the state agency that it was acquired for under one million dollars (\$1,000,000) on or before January 1, 2010, and was in operation on or before July 1, 2010.
- (11) "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies, and insurance companies), state or political subdivision, or instrumentality of a state.
- (12) "Predevelopment activities" means expenditures for architectural designs, plans, working drawings, and specifications, site acquisition, professional consultations, preliminary plans, studies, and surveys made in preparation for the offering of a new, institutional health

1	service.
2	(13) "State agency" means the Rhode Island state department of health.
3	(14) "To develop" means to undertake those activities that, on their completion, will result
4	in the offering of a new, institutional health service or new healthcare equipment or the incurring
5	of a financial obligation, in relation to the offering of that service.
6	(15) "To offer" means to hold oneself out as capable of providing, or as having the means
7	for the provision of, specified health services or healthcare equipment.
8	SECTION 4. This act shall take effect upon passage.

LC002146/SUB A/2

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

AN ACT

RELATING TO HEALTH AND SAFETY
