3 lr 2303 CF 3 lr 2673

By: Delegate Reznik

Introduced and read first time: February 8, 2013 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Medical Spa Facilities - Licensing Requirements

FOR the purpose of prohibiting a medical spa facility from operating in the State unless the medical spa facility holds a license issued by the Secretary of Health and Mental Hygiene; requiring the Secretary to set certain application and renewal fees; requiring the Secretary to issue a license to an applicant that meets certain requirements; prohibiting the transfer of a license; requiring a license to be displayed in a certain manner; requiring an applicant for a license to pay a certain application fee and submit an application to the Secretary on a certain form; requiring the application to include certain items; requiring the owner of a medical spa facility to submit an application and obtain a separate license for each medical spa facility to be operated; providing for the expiration and renewal of a license; requiring the Secretary to conduct a random inspection of each licensed medical spa facility with a certain frequency and for certain purposes; authorizing the Secretary to conduct certain inspections of a licensed medical spa facility for certain purposes; requiring a licensed medical spa facility to allow certain access; requiring the Secretary and a licensed medical spa facility to make the results of a certain inspection available to the public on request; requiring the Secretary to adopt regulations for certain purposes; authorizing the Secretary to deny a license and take certain actions relating to a license of a licensee under certain circumstances; requiring the Secretary to provide the opportunity for a hearing in accordance with the Administrative Procedure Act under certain circumstances; establishing certain penalties for violations of certain provisions of this Act or certain regulations; requiring the Secretary to adopt regulations that establish standards for the imposition of a certain penalty; defining certain terms; and generally relating to licensing medical spa facilities and the Secretary of Health and Mental Hygiene.

BY adding to

29 Article – Health – General

1 2 3 4	Section 19–3C–01 through 19–3C–09 to be under the new subtitle "Subtitle 3C. Medical Spa Facilities" Annotated Code of Maryland (2009 Replacement Volume and 2012 Supplement)
5 6	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
7	Article - Health - General
8	SUBTITLE 3C. MEDICAL SPA FACILITIES.
9	19-3C-01.
10 11	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
12	(B) (1) "COSMETIC MEDICAL PROCEDURE" MEANS A PROCEDURE
13	USING A COSMETIC MEDICAL DEVICE OR MEDICAL PRODUCT TO IMPROVE AN
14	INDIVIDUAL'S APPEARANCE.
15	(2) "COSMETIC MEDICAL PROCEDURE" INCLUDES:
16	(I) SKIN TREATMENTS USING LASERS;
17	(II) SKIN TREATMENTS USING INTENSE PULSED LIGHT;
18	(III) SKIN TREATMENTS USING RADIO FREQUENCIES,
19	MICROWAVES, OR ELECTRIC PULSES;
20	(IV) DEEP SKIN PEELS;
21	(V) SKIN TREATMENTS WITH PHOTOTHERAPY;
22	(VI) MICRODERMABRASION;
23	(VII) SUBCUTANEOUS, INTRADERMAL, OR INTRAMUSCULAR
24	INJECTIONS OF MEDICAL PRODUCTS;
25	(VIII) TREATMENTS INTENDED TO REMOVE OR CAUSE
26	DESTRUCTION OF FAT; AND
27	(IX) ANY TREATMENT USING A COSMETIC MEDICAL DEVICE
28	FOR THE PURPOSE OF IMPROVING AN INDIVIDUAL'S APPEARANCE.

- 1 (C) (1) "COSMETIC SURGICAL PROCEDURE" MEANS THE USE OF SURGICAL SERVICES TO RESHAPE THE STRUCTURE OF A HUMAN BODY TO CHANGE THE APPEARANCE OF AN INDIVIDUAL.
- 4 (2) "COSMETIC SURGICAL PROCEDURE" DOES NOT INCLUDE:
- 5 (I) A PROCEDURE DONE UNDER LOCAL ANESTHESIA OR
- 6 MILD SEDATION; OR
- 7 (II) LIPOSUCTION THAT REMOVES LESS THAN 1,000 CUBIC
- 8 CENTIMETERS OF ASPIRATE.
- 9 (D) "MEDICAL SPA DIRECTOR" MEANS A LICENSED PHYSICIAN WHO 10 DIRECTS OR SERVES AS THE MEDICAL ADVISOR FOR A MEDICAL SPA FACILITY.
- 11 (E) "MEDICAL SPA FACILITY" MEANS ANY ENTITY, HOWEVER
- 12 ORGANIZED, IN WHICH A COSMETIC MEDICAL PROCEDURE OR A COSMETIC
- 13 SURGICAL PROCEDURE IS PERFORMED.
- 14 **19–3C–02.**
- 15 THIS SUBTITLE DOES NOT APPLY TO:
- 16 (1) A HEALTH CARE FACILITY THAT HOLDS A LICENSE UNDER
- 17 THIS TITLE;
- 18 (2) THE PRACTICE OF COSMETOLOGY OR ELECTROLOGY,
- 19 WHETHER IN A SEPARATE FACILITY OR IN A MEDICAL SPA FACILITY; OR
- 20 (3) A CLINIC OR MEDICAL PRACTICE THAT PROVIDES COSMETIC
- 21 MEDICAL PROCEDURES OR COSMETIC SURGICAL PROCEDURES AS PART OF OR
- 22 INCIDENT TO ITS OTHER MEDICAL SERVICES, AS DETERMINED BY THE
- 23 **DEPARTMENT.**
- 24 **19–3C–03**.
- 25 (A) A MEDICAL SPA FACILITY MAY NOT OPERATE IN THE STATE UNLESS 26 THE MEDICAL SPA FACILITY HOLDS A LICENSE ISSUED BY THE SECRETARY.
- 27 (B) THE SECRETARY SHALL SET REASONABLE APPLICATION AND
- 28 RENEWAL FEES NOT TO EXCEED THE ADMINISTRATIVE COSTS OF LICENSING
- 29 AND INSPECTION.

1 (C)	THE S	SECRETARY	SHALL	ISSUE .	A]	LICENSE	TO	AN	APPLIC	ANT	THA'	Ι
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- 2 MEETS THE REQUIREMENTS OF THIS SUBTITLE AND ALL APPLICABLE
- 3 REGULATIONS ADOPTED BY THE SECRETARY.
- 4 (D) A LICENSE ISSUED UNDER THIS SUBTITLE IS NOT TRANSFERABLE.
- 5 (E) A MEDICAL SPA FACILITY LICENSE SHALL BE DISPLAYED
- 6 CONSPICUOUSLY IN THE PLACE OF BUSINESS FOR WHICH THE LICENSE IS
- 7 ISSUED.
- 8 **19–3C–04**.
- 9 (A) AN APPLICANT FOR A MEDICAL SPA FACILITY LICENSE SHALL:
- 10 (1) PAY TO THE SECRETARY AN APPLICATION FEE SET BY THE
- 11 SECRETARY; AND
- 12 (2) SUBMIT AN APPLICATION TO THE SECRETARY ON THE FORM
- 13 THAT THE SECRETARY REQUIRES.
- 14 (B) THE APPLICATION SHALL INCLUDE:
- 15 (1) THE NAME, FULL BUSINESS ADDRESS, AND TELEPHONE
- 16 NUMBER OF THE APPLICANT;
- 17 (2) ALL TRADE OR BUSINESS NAMES USED BY THE APPLICANT;
- 18 (3) THE TYPE OF BUSINESS FORM UNDER WHICH THE APPLICANT
- 19 OPERATES, SUCH AS PARTNERSHIP, CORPORATION, OR SOLE PROPRIETORSHIP;
- 20 (4) THE NAME OF EACH OWNER OF THE APPLICANT;
- 21 (5) THE NAME AND PHYSICIAN LICENSE NUMBER OF THE
- 22 MEDICAL SPA DIRECTOR;
- 23 (6) The names and physician license numbers of all
- 24 SUPERVISING PHYSICIANS;
- 25 (7) A LIST OF ALL MEDICAL DEVICES TO BE USED AT THE
- 26 MEDICAL SPA FACILITY; AND

- 5 A LIST OF ALL COSMETIC MEDICAL PROCEDURES AND ALL 1 2 COSMETIC SURGICAL PROCEDURES TO BE PERFORMED AT THE MEDICAL SPA 3 FACILITY. 4 (C) AN OWNER OF A MEDICAL SPA FACILITY SHALL SUBMIT AN 5 APPLICATION AND OBTAIN A SEPARATE LICENSE FOR EACH MEDICAL SPA 6 FACILITY TO BE OPERATED. 7 19-3C-05. 8 (A) A LICENSE EXPIRES ON THE THIRD ANNIVERSARY OF ITS 9 EFFECTIVE DATE, UNLESS THE LICENSE IS RENEWED FOR A 3-YEAR TERM AS PROVIDED IN THIS SECTION. 10 11 BEFORE THE LICENSE EXPIRES, A LICENSE MAY BE RENEWED FOR 12AN ADDITIONAL 3-YEAR TERM IF THE APPLICANT: **(1)** 13 OTHERWISE IS ENTITLED TO THE LICENSE; 14 PAYS TO THE SECRETARY THE RENEWAL FEE SET BY THE 15 SECRETARY; AND SUBMITS TO THE SECRETARY: 16 **(3)** A RENEWAL APPLICATION ON THE FORM THAT THE 17 (I)18 SECRETARY REQUIRES; AND 19 (II) SATISFACTORY EVIDENCE OF COMPLIANCE WITH ANY 20 REQUIREMENT UNDER THIS SUBTITLE FOR LICENSE RENEWAL. 21THE SECRETARY SHALL RENEW A LICENSE IF THE APPLICANT 22 MEETS THE REQUIREMENTS OF THIS SECTION. 23 19-3C-06.
- THE SECRETARY: 24(A)
- 25**(1)** SHALL CONDUCT A RANDOM INSPECTION OF EACH LICENSED 26MEDICAL SPA FACILITY:
- 27(I)WITHIN THE FIRST 6 MONTHS AFTER THE MEDICAL SPA 28FACILITY BEGINS OPERATIONS; AND

1	(II) AT LEAST EVERY 3 YEARS THEREAFTER; AND
2 3	(2) MAY CONDUCT AN INSPECTION OF A LICENSED MEDICAL SPA FACILITY:
4 5	(I) TO VERIFY COMPLIANCE WITH LICENSING REQUIREMENTS; AND
6	(II) TO INVESTIGATE COMPLAINTS.
7 8 9	(B) A LICENSED MEDICAL SPA FACILITY SHALL ALLOW ACCESS TO ALL PARTS OF THE MEDICAL SPA FACILITY AND ALL PERTINENT RECORDS REQUIRED FOR INSPECTION.
10 11 12	(C) THE SECRETARY AND A LICENSED MEDICAL SPA FACILITY SHALL MAKE THE RESULTS OF AN INSPECTION CONDUCTED UNDER SUBSECTION (A) AVAILABLE TO THE PUBLIC ON REQUEST.
13	19-3C-07.
14	THE SECRETARY SHALL ADOPT REGULATIONS TO:
15 16	(1) ESTABLISH STANDARDS AND PROCEDURES TO ENSURE QUALITY OF CARE AND PATIENT SAFETY, INCLUDING:
17 18 19	(I) QUALIFICATIONS, TRAINING, AND RESPONSIBILITIES OF MEDICAL SPA DIRECTORS, SUPERVISING PHYSICIANS, AND OTHER PERSONNEL;
20 21 22	(II) STANDARDS FOR DELEGATION OF COSMETIC MEDICAL PROCEDURES AND COSMETIC SURGICAL PROCEDURES TO NONPHYSICIAN PERSONNEL;
23	(III) PROCEDURES FOR CREDENTIALING AND PEER REVIEW;
24	(IV) EMERGENCY PLANS AND PROCEDURES;
25 26	(V) STANDARDS AND PROCEDURES FOR SANITATION AND HAZARDOUS WASTE DISPOSAL;
2627	(VI) FACILITY AND BUILDING STANDARDS;

1		(VII)	Q UALITY	CONTROLS	FOR	ANY	MEDICAL	DEVICES	OR
2	EQUIPMENT;								

- 3 (VIII) PROCEDURES FOR PATIENT RECOVERY, DISCHARGE,
- 4 AND FOLLOW-UP;
- 5 (IX) REPORTING OF ADVERSE EVENTS; AND
- 6 (X) ANY OTHER STANDARDS OR PROCEDURES THE 7 SECRETARY CONSIDERS NECESSARY FOR QUALITY OF CARE AND PATIENT 8 SAFETY; AND
- 9 (2) CARRY OUT THIS SUBTITLE.
- 10 **19–3C–08.**
- 11 (A) THE SECRETARY MAY DENY A LICENSE TO ANY APPLICANT, OR
- 12 SUSPEND, RESTRICT, OR REVOKE A LICENSE IF THE APPLICANT OR LICENSEE
- 13 FAILS TO MEET THE REQUIREMENTS OF THIS SUBTITLE OR ANY REGULATION
- 14 ADOPTED UNDER THIS SUBTITLE.
- 15 (B) (1) BEFORE DENYING, SUSPENDING, RESTRICTING, OR REVOKING
- 16 A LICENSE UNDER THIS SECTION, THE SECRETARY SHALL PROVIDE THE
- 17 APPLICANT OR LICENSEE AN OPPORTUNITY FOR A HEARING.
- 18 (2) THE SECRETARY SHALL GIVE NOTICE AND HOLD THE
- 19 HEARING IN ACCORDANCE WITH THE ADMINISTRATIVE PROCEDURE ACT.
- 20 **19–3C–09.**
- 21 (A) (1) A PERSON WHO VIOLATES ANY PROVISION OF THIS SUBTITLE
- 22 OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE IS GUILTY OF A
- 23 MISDEMEANOR AND ON CONVICTION IS SUBJECT TO A PENALTY NOT EXCEEDING
- \$1,000 OR IMPRISONMENT NOT EXCEEDING 1 YEAR OR BOTH.
- 25 (2) EACH DAY A VIOLATION CONTINUES AFTER THE FIRST
- 26 CONVICTION IS A SEPARATE OFFENSE.
- 27 (B) (1) IN ADDITION TO THE PROVISIONS OF SUBSECTION (A) OF THIS
- 28 SECTION, THE SECRETARY MAY IMPOSE AN ADMINISTRATIVE PENALTY OF UP
- 29 TO \$1,000 FOR A VIOLATION OF ANY PROVISION OF THIS SUBTITLE OR ANY
- 30 REGULATION ADOPTED UNDER THIS SUBTITLE.

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- 1 (2) THE SECRETARY SHALL ADOPT REGULATIONS THAT 2 ESTABLISH STANDARDS FOR THE IMPOSITION OF AN ADMINISTRATIVE PENALTY 3 UNDER PARAGRAPH (1) OF THIS SUBSECTION.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 5 October 1, 2013.