

HOUSE BILL 1009

J3

3lr2303
CF 3lr2673

By: **Delegate Reznik**

Introduced and read first time: February 8, 2013

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 25, 2013

CHAPTER _____

1 AN ACT concerning

2 ~~**Medical Spa Facilities – Licensing Requirements**~~
3 ~~**Cosmetic Surgical Facilities – Regulation**~~

4 FOR the purpose of ~~prohibiting a medical spa facility from operating in the State~~
5 ~~unless the medical spa facility holds a license issued by the Secretary of Health~~
6 ~~and Mental Hygiene; requiring the Secretary to set certain application and~~
7 ~~renewal fees; requiring the Secretary to issue a license to an applicant that~~
8 ~~meets certain requirements; prohibiting the transfer of a license; requiring a~~
9 ~~license to be displayed in a certain manner; requiring an applicant for a license~~
10 ~~to pay a certain application fee and submit an application to the Secretary on a~~
11 ~~certain form; requiring the application to include certain items; requiring the~~
12 ~~owner of a medical spa facility to submit an application and obtain a separate~~
13 ~~license for each medical spa facility to be operated; providing for the expiration~~
14 ~~and renewal of a license; requiring the Secretary to conduct a random inspection~~
15 ~~of each licensed medical spa facility with a certain frequency and for certain~~
16 ~~purposes; authorizing the Secretary to conduct certain inspections of a licensed~~
17 ~~medical spa facility for certain purposes; requiring a licensed medical spa~~
18 ~~facility to allow certain access; requiring the Secretary and a licensed medical~~
19 ~~spa facility to make the results of a certain inspection available to the public on~~
20 ~~request; requiring the Secretary to adopt regulations for certain purposes;~~
21 ~~authorizing the Secretary to deny a license and take certain actions relating to a~~
22 ~~license of a licensee under certain circumstances; requiring the Secretary to~~
23 ~~provide the opportunity for a hearing in accordance with the Administrative~~
24 ~~Procedure Act under certain circumstances; establishing certain penalties for~~
25 ~~violations of certain provisions of this Act or certain regulations; requiring the~~

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



~~Secretary to adopt regulations that establish standards for the imposition of a certain penalty; authorizing the Secretary of Health and Mental Hygiene to adopt certain regulations for cosmetic surgical facilities; authorizing the Secretary to investigate certain complaints relating to cosmetic surgical facilities; requiring certain complaints to be referred to certain health occupations boards; altering a certain definition; defining certain terms; and generally relating to licensing medical spa regulating cosmetic surgical facilities and the Secretary of Health and Mental Hygiene.~~

BY adding to

Article – Health – General

Section 19-3C-01 through ~~19-3C-09~~ 19-3C-03 to be under the new subtitle

“Subtitle 3C. ~~Medical Spa~~ Cosmetic Surgical Facilities”

Annotated Code of Maryland

(2009 Replacement Volume and 2012 Supplement)

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section 14-101(d)

Annotated Code of Maryland

(2009 Replacement Volume and 2012 Supplement)

Preamble

WHEREAS, Licensure of ambulatory surgical centers may exclude offices and facilities in which cosmetic surgical procedures are performed; and

WHEREAS, The authority of the Board of Physicians to discipline licensees who perform cosmetic surgical procedures excludes specified procedures and only responds to specific complaints; and

WHEREAS, The infections, subsequent hospitalizations, and, in the case of one individual, death among individuals who had undergone liposuction at a medical spa in the State exposed weaknesses in the State’s regulation of offices and facilities in which cosmetic surgical procedures are performed; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 3C. ~~MEDICAL SPA~~ COSMETIC SURGICAL FACILITIES.

19-3C-01.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

1 ~~(B) (1) “COSMETIC MEDICAL PROCEDURE” MEANS A PROCEDURE~~
2 ~~USING A COSMETIC MEDICAL DEVICE OR MEDICAL PRODUCT TO IMPROVE AN~~
3 ~~INDIVIDUAL’S APPEARANCE.~~

4 ~~(2) “COSMETIC MEDICAL PROCEDURE” INCLUDES:~~

5 ~~(I) SKIN TREATMENTS USING LASERS;~~

6 ~~(II) SKIN TREATMENTS USING INTENSE PULSED LIGHT;~~

7 ~~(III) SKIN TREATMENTS USING RADIO FREQUENCIES,~~
8 ~~MICROWAVES, OR ELECTRIC PULSES;~~

9 ~~(IV) DEEP SKIN PEELS;~~

10 ~~(V) SKIN TREATMENTS WITH PHOTOTHERAPY;~~

11 ~~(VI) MICRODERMABRASION;~~

12 ~~(VII) SUBCUTANEOUS, INTRADERMAL, OR INTRAMUSCULAR~~
13 ~~INJECTIONS OF MEDICAL PRODUCTS;~~

14 ~~(VIII) TREATMENTS INTENDED TO REMOVE OR CAUSE~~
15 ~~DESTRUCTION OF FAT; AND~~

16 ~~(IX) ANY TREATMENT USING A COSMETIC MEDICAL DEVICE~~
17 ~~FOR THE PURPOSE OF IMPROVING AN INDIVIDUAL’S APPEARANCE.~~

18 (B) (1) “COSMETIC SURGICAL FACILITY” MEANS AN OFFICE OR A
19 FACILITY IN WHICH A COSMETIC SURGICAL PROCEDURE IS PERFORMED.

20 (2) “COSMETIC SURGICAL FACILITY” DOES NOT INCLUDE:

21 (I) AN AMBULATORY SURGICAL FACILITY REGULATED
22 UNDER SUBTITLE 3B OF THIS TITLE;

23 (II) A HOSPITAL REGULATED UNDER SUBTITLE 3 OF THIS
24 TITLE; OR

25 (III) AN OFFICE OWNED OR OPERATED BY ONE OR MORE
26 DENTISTS PROVIDING SERVICES WITHIN THE SCOPE OF PRACTICE OF
27 DENTISTRY UNDER TITLE 4 OF THE HEALTH OCCUPATIONS ARTICLE.

1 (C) (1) "COSMETIC SURGICAL PROCEDURE" MEANS THE USE OF
2 SURGICAL SERVICES TO RESHAPE THE STRUCTURE OF A HUMAN BODY TO
3 CHANGE THE APPEARANCE OF AN INDIVIDUAL.

4 (2) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS
5 SUBSECTION, "COSMETIC COSMETIC SURGICAL PROCEDURE" DOES NOT
6 INCLUDE:

7 (I) A PROCEDURE DONE UNDER LOCAL ANESTHESIA OR
8 MILD SEDATION; OR

9 (II) LIPOSUCTION THAT REMOVES LESS THAN 1,000 CUBIC
10 CENTIMETERS OF ASPIRATE.

11 (3) "COSMETIC SURGICAL PROCEDURE" INCLUDES ANY
12 PROCEDURE UNDER PARAGRAPH (2) OF THIS SUBSECTION THAT, UNDER THE
13 CIRCUMSTANCES ESTABLISHED BY THE SECRETARY IN REGULATIONS ADOPTED
14 UNDER § 19-3C-02(D) OF THIS SUBTITLE, IS A COSMETIC SURGICAL
15 PROCEDURE.

16 ~~(D) "MEDICAL SPA DIRECTOR" MEANS A LICENSED PHYSICIAN WHO~~
17 ~~DIRECTS OR SERVES AS THE MEDICAL ADVISOR FOR A MEDICAL SPA FACILITY.~~

18 ~~(E) "MEDICAL SPA FACILITY" MEANS ANY ENTITY, HOWEVER~~
19 ~~ORGANIZED, IN WHICH A COSMETIC MEDICAL PROCEDURE OR A COSMETIC~~
20 ~~SURGICAL PROCEDURE IS PERFORMED.~~

21 ~~19-3C-02.~~

22 ~~THIS SUBTITLE DOES NOT APPLY TO:~~

23 ~~(1) A HEALTH CARE FACILITY THAT HOLDS A LICENSE UNDER~~
24 ~~THIS TITLE;~~

25 ~~(2) THE PRACTICE OF COSMETOLOGY OR ELECTROLOGY,~~
26 ~~WHETHER IN A SEPARATE FACILITY OR IN A MEDICAL SPA FACILITY; OR~~

27 ~~(3) A CLINIC OR MEDICAL PRACTICE THAT PROVIDES COSMETIC~~
28 ~~MEDICAL PROCEDURES OR COSMETIC SURGICAL PROCEDURES AS PART OF OR~~
29 ~~INCIDENT TO ITS OTHER MEDICAL SERVICES, AS DETERMINED BY THE~~
30 ~~DEPARTMENT.~~

31 ~~19-3C-03.~~

1 ~~(A) A MEDICAL SPA FACILITY MAY NOT OPERATE IN THE STATE UNLESS~~
2 ~~THE MEDICAL SPA FACILITY HOLDS A LICENSE ISSUED BY THE SECRETARY.~~

3 ~~(B) THE SECRETARY SHALL SET REASONABLE APPLICATION AND~~
4 ~~RENEWAL FEES NOT TO EXCEED THE ADMINISTRATIVE COSTS OF LICENSING~~
5 ~~AND INSPECTION.~~

6 ~~(C) THE SECRETARY SHALL ISSUE A LICENSE TO AN APPLICANT THAT~~
7 ~~MEETS THE REQUIREMENTS OF THIS SUBTITLE AND ALL APPLICABLE~~
8 ~~REGULATIONS ADOPTED BY THE SECRETARY.~~

9 ~~(D) A LICENSE ISSUED UNDER THIS SUBTITLE IS NOT TRANSFERABLE.~~

10 ~~(E) A MEDICAL SPA FACILITY LICENSE SHALL BE DISPLAYED~~
11 ~~CONSPICUOUSLY IN THE PLACE OF BUSINESS FOR WHICH THE LICENSE IS~~
12 ~~ISSUED.~~

13 ~~19-3C-04.~~

14 ~~(A) AN APPLICANT FOR A MEDICAL SPA FACILITY LICENSE SHALL:~~

15 ~~(1) PAY TO THE SECRETARY AN APPLICATION FEE SET BY THE~~
16 ~~SECRETARY; AND~~

17 ~~(2) SUBMIT AN APPLICATION TO THE SECRETARY ON THE FORM~~
18 ~~THAT THE SECRETARY REQUIRES.~~

19 ~~(B) THE APPLICATION SHALL INCLUDE:~~

20 ~~(1) THE NAME, FULL BUSINESS ADDRESS, AND TELEPHONE~~
21 ~~NUMBER OF THE APPLICANT;~~

22 ~~(2) ALL TRADE OR BUSINESS NAMES USED BY THE APPLICANT;~~

23 ~~(3) THE TYPE OF BUSINESS FORM UNDER WHICH THE APPLICANT~~
24 ~~OPERATES, SUCH AS PARTNERSHIP, CORPORATION, OR SOLE PROPRIETORSHIP;~~

25 ~~(4) THE NAME OF EACH OWNER OF THE APPLICANT;~~

26 ~~(5) THE NAME AND PHYSICIAN LICENSE NUMBER OF THE~~
27 ~~MEDICAL SPA DIRECTOR;~~

28 ~~(6) THE NAMES AND PHYSICIAN LICENSE NUMBERS OF ALL~~
29 ~~SUPERVISING PHYSICIANS;~~

1 ~~(7) A LIST OF ALL MEDICAL DEVICES TO BE USED AT THE~~
2 ~~MEDICAL SPA FACILITY; AND~~

3 ~~(8) A LIST OF ALL COSMETIC MEDICAL PROCEDURES AND ALL~~
4 ~~COSMETIC SURGICAL PROCEDURES TO BE PERFORMED AT THE MEDICAL SPA~~
5 ~~FACILITY.~~

6 ~~(C) AN OWNER OF A MEDICAL SPA FACILITY SHALL SUBMIT AN~~
7 ~~APPLICATION AND OBTAIN A SEPARATE LICENSE FOR EACH MEDICAL SPA~~
8 ~~FACILITY TO BE OPERATED.~~

9 ~~19-3C-05.~~

10 ~~(A) A LICENSE EXPIRES ON THE THIRD ANNIVERSARY OF ITS~~
11 ~~EFFECTIVE DATE, UNLESS THE LICENSE IS RENEWED FOR A 3 YEAR TERM AS~~
12 ~~PROVIDED IN THIS SECTION.~~

13 ~~(B) BEFORE THE LICENSE EXPIRES, A LICENSE MAY BE RENEWED FOR~~
14 ~~AN ADDITIONAL 3 YEAR TERM IF THE APPLICANT:~~

15 ~~(1) OTHERWISE IS ENTITLED TO THE LICENSE;~~

16 ~~(2) PAYS TO THE SECRETARY THE RENEWAL FEE SET BY THE~~
17 ~~SECRETARY; AND~~

18 ~~(3) SUBMITS TO THE SECRETARY;~~

19 ~~(I) A RENEWAL APPLICATION ON THE FORM THAT THE~~
20 ~~SECRETARY REQUIRES; AND~~

21 ~~(II) SATISFACTORY EVIDENCE OF COMPLIANCE WITH ANY~~
22 ~~REQUIREMENT UNDER THIS SUBTITLE FOR LICENSE RENEWAL.~~

23 ~~(C) THE SECRETARY SHALL RENEW A LICENSE IF THE APPLICANT~~
24 ~~MEETS THE REQUIREMENTS OF THIS SECTION.~~

25 ~~19-3C-06.~~

26 ~~(A) THE SECRETARY:~~

27 ~~(1) SHALL CONDUCT A RANDOM INSPECTION OF EACH LICENSED~~
28 ~~MEDICAL SPA FACILITY;~~

1 ~~(I) WITHIN THE FIRST 6 MONTHS AFTER THE MEDICAL SPA~~
2 ~~FACILITY BEGINS OPERATIONS; AND~~

3 ~~(II) AT LEAST EVERY 3 YEARS THEREAFTER; AND~~

4 ~~(2) MAY CONDUCT AN INSPECTION OF A LICENSED MEDICAL SPA~~
5 ~~FACILITY;~~

6 ~~(I) TO VERIFY COMPLIANCE WITH LICENSING~~
7 ~~REQUIREMENTS; AND~~

8 ~~(II) TO INVESTIGATE COMPLAINTS.~~

9 ~~(B) A LICENSED MEDICAL SPA FACILITY SHALL ALLOW ACCESS TO ALL~~
10 ~~PARTS OF THE MEDICAL SPA FACILITY AND ALL PERTINENT RECORDS~~
11 ~~REQUIRED FOR INSPECTION.~~

12 ~~(C) THE SECRETARY AND A LICENSED MEDICAL SPA FACILITY SHALL~~
13 ~~MAKE THE RESULTS OF AN INSPECTION CONDUCTED UNDER SUBSECTION (A)~~
14 ~~AVAILABLE TO THE PUBLIC ON REQUEST.~~

15 ~~19-3C-07.~~

16 ~~THE SECRETARY SHALL ADOPT REGULATIONS TO:~~

17 ~~(1) ESTABLISH STANDARDS AND PROCEDURES TO ENSURE~~
18 ~~QUALITY OF CARE AND PATIENT SAFETY, INCLUDING:~~

19 ~~(I) QUALIFICATIONS, TRAINING, AND RESPONSIBILITIES~~
20 ~~OF MEDICAL SPA DIRECTORS, SUPERVISING PHYSICIANS, AND OTHER~~
21 ~~PERSONNEL;~~

22 ~~(II) STANDARDS FOR DELEGATION OF COSMETIC MEDICAL~~
23 ~~PROCEDURES AND COSMETIC SURGICAL PROCEDURES TO NONPHYSICIAN~~
24 ~~PERSONNEL;~~

25 ~~(III) PROCEDURES FOR CREDENTIALING AND PEER REVIEW;~~

26 ~~(IV) EMERGENCY PLANS AND PROCEDURES;~~

27 ~~(V) STANDARDS AND PROCEDURES FOR SANITATION AND~~
28 ~~HAZARDOUS WASTE DISPOSAL;~~

29 ~~(VI) FACILITY AND BUILDING STANDARDS;~~

1 ~~(VII) QUALITY 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~~
24 ~~\$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.~~

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.~~

4 19-3C-02.

5 (A) THE SECRETARY MAY ADOPT REGULATIONS FOR COSMETIC
6 SURGICAL FACILITIES IN THE STATE.

7 (B) REGULATIONS ADOPTED BY THE SECRETARY UNDER THIS SECTION
8 SHALL INCLUDE DEEMING A COSMETIC SURGICAL FACILITY TO MEET SPECIFIED
9 REQUIREMENTS, IF THE COSMETIC SURGICAL FACILITY IS ACCREDITED BY:

10 (1) THE AMERICAN ASSOCIATION FOR ACCREDITATION OF
11 AMBULATORY SURGICAL FACILITIES;

12 (2) THE ACCREDITATION ASSOCIATION FOR AMBULATORY
13 HEALTH CARE;

14 (3) THE JOINT COMMISSION; OR

15 (4) ANY OTHER ACCREDITATION ORGANIZATION, AS
16 DETERMINED BY THE SECRETARY.

17 (C) REGULATIONS ADOPTED UNDER THIS SECTION MAY NOT REQUIRE
18 HIGHER STANDARDS FOR COSMETIC SURGICAL FACILITIES THAN THE
19 STANDARDS REQUIRED FOR AMBULATORY SURGICAL FACILITIES UNDER
20 SUBTITLE 3B OF THIS TITLE.

21 (D) (1) THE SECRETARY MAY ADOPT REGULATIONS THAT ESTABLISH
22 THE CIRCUMSTANCES UNDER WHICH A PROCEDURE IS A “COSMETIC SURGICAL
23 PROCEDURE” UNDER § 19-3C-01(C)(3) OF THIS SUBTITLE.

24 (2) THE REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS
25 SUBSECTION SHALL BE BASED ON A FINDING BY THE SECRETARY THAT THE
26 PROCEDURE RAISES SUBSTANTIAL HEALTH AND SAFETY CONCERNS THAT
27 WARRANT REGULATION OF THE PROCEDURE UNDER THIS SUBTITLE.

28 (3) IN ADOPTING REGULATIONS UNDER PARAGRAPH (1) OF THIS
29 SUBSECTION, THE SECRETARY SHALL CONSIDER AVAILABLE STUDIES,
30 REPORTS, AND OTHER LITERATURE RELATED TO:

31 (1) THE SAFETY OR RISKS OF THE PROCEDURE;

1 (II) THE EDUCATION AND TRAINING OF THE HEALTH CARE
 2 PRACTITIONERS ADMINISTERING ANESTHESIA FOR THE PROCEDURE;

3 (III) THE EDUCATION AND TRAINING OF THE HEALTH CARE
 4 PRACTITIONERS PERFORMING THE PROCEDURE; AND

5 (IV) THE SETTING IN WHICH THE PROCEDURE IS
 6 PERFORMED.

7 19-3C-03.

8 (A) THE SECRETARY MAY INVESTIGATE COMPLAINTS CONCERNING THE
 9 CONFORMANCE OF A COSMETIC SURGICAL FACILITY TO THE REQUIREMENTS OF
 10 REGULATIONS ADOPTED UNDER § 19-3C-02 OF THIS SUBTITLE.

11 (B) IF THE COMPLAINT CONCERNS HEALTH CARE PRACTITIONER
 12 PERFORMANCE OR STANDARDS OF MEDICAL PRACTICE, THE COMPLAINT SHALL
 13 BE REFERRED TO THE APPROPRIATE HEALTH OCCUPATIONS BOARD THAT
 14 LICENSES, CERTIFIES, OR OTHERWISE REGULATES THE HEALTH CARE
 15 PRACTITIONER UNDER THE HEALTH OCCUPATIONS ARTICLE.

16 Article – Health Occupations

17 14-101.

18 (d) (1) “Cosmetic surgical procedure” means the use of surgical services to
 19 reshape the structure of a human body in order to change the appearance of an
 20 individual.

21 (2) [“Cosmetic] EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS
 22 SUBSECTION, “COSMETIC surgical procedure” does not include:

23 (i) A procedure done under local anesthesia or mild sedation; or

24 (ii) Liposuction that removes less than 1,000 cubic centimeters
 25 of aspirate.

26 (3) “COSMETIC SURGICAL PROCEDURE” INCLUDES ANY
 27 PROCEDURE UNDER PARAGRAPH (2) OF THIS SUBSECTION THAT, UNDER THE
 28 CIRCUMSTANCES ESTABLISHED BY THE SECRETARY IN REGULATIONS ADOPTED
 29 UNDER TITLE 19, SUBTITLE 3C OF THE HEALTH – GENERAL ARTICLE, IS A
 30 COSMETIC SURGICAL PROCEDURE.

31 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
 32 October 1, 2013.