IN THE MATTER OF
IRENE HANZIGIANNIS

Respondent

Unlicensed

* BEFORE THE

* MARYLAND STATE

* BOARD OF PHYSICIANS

* Case Number: 2015-0856B

CONSENT ORDER

The Maryland State Board of Physicians (the "Board") voted to charge **IRENE HANZIGIANNIS** (the "Respondent") with violating the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. II ("Health Occ. II") §§ 14-101 *et seq.* (2014 Repl. Vol.) and Md. Code Regs. ("COMAR") 10.32.09 *et seq.*

Specifically, the Board voted to charge the Respondent with violating the following provisions of the Act and COMAR:

Health Occ. II § 14-601. Practicing without license.

Except as otherwise provided in this title, a person may not practice, attempt to practice, or offer to practice medicine in this State unless licensed by the Board.

COMAR 10.32.09

.02 Definitions

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
 - (4) Cosmetic Medical Device.
 - (a) "Cosmetic Medical Device" means a device that alters or damages living tissue.
 - (b) "Cosmetic Medical Device" includes any of the following items, when the item is used for cosmetic purposes:

- (ii) Device emitting light or intense pulse light[.]
- (5) Cosmetic Medical Procedure.
 - (a) "Cosmetic medical procedure" means a procedure using a cosmetic medical device or medical product to improve an individual's appearance.
 - (b) "Cosmetic medical procedure" includes the following:
 - (ii) Skin treatment using intense pulsed light; [and]
 - (ix) Any treatment using a cosmetic medical device for the purpose of improving an individual's appearance.

.09 Grounds for Discipline

C. Other individual. An individual using a cosmetic medical device or performing a cosmetic medical procedure who is not a licensed physician and is not authorized to perform the cosmetic medical procedure under this chapter, or under regulations promulgated by another licensing board established by Health Occupations Article, Annotated Code of Maryland, is guilty of the practice of medicine without a license and may be subject to a fine of not more than \$50,000 under Health Occupations Article, § 14-606, Annotated Code of Maryland.

Prior to the issuance of charges, the Respondent agreed to enter into this public Consent Order consisting of Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

The Board makes the following Findings of Fact:

BACKGROUND

1. At all times relevant hereto, the Respondent was not and never had been licensed by any health occupations board in the State of Maryland.

2. At all times relevant hereto, the Respondent was employed as an aesthetician by a dermatology practice ("Practice A")¹ with offices throughout Maryland. The Respondent was hired as an aesthetician to assist a physician ("Physician A") at Practice A's office in Glen Burnie, Maryland in or around August 2013.

THE COMPLAINT

- 3. On or about December 17, 2014, the Board received an anonymous complaint from an individual who alleged that "Intense Pulse Light treatments were performed by someone who was not a nurse, physician's assistant, nurse practitioner, or doctor under the supervision and knowledge of [Physician A]." The anonymous complainant further alleged that laser hair removal and skin rejuvenation were also being performed by unlicensed individuals under the Respondent's supervision.
- 4. Based on the complaint, Panel B initiated an investigation of the Respondent.

BOARD INVESTIGATION

- 5. Board staff conducted an unannounced visit of Practice A on or about May 7, 2015, and pursuant to subpoenas, obtained Physician A's appointment logs, ten (10) patient records selected from the appointment logs, a list of employees at Practice A and nineteen (19) personnel files selected from the employees list.
- 6. By letter, dated May 8, 2015, Physician A provided the Board a written response to the complaint. In his letter, Physician A denied having laser cosmetic medical devices in Practice A's Glen Burnie location. Physician A admitted that Practice

¹ To ensure confidentiality, the names of individuals, hospitals and healthcare facilities involved in this case are not disclosed in this document.

A's Glen Burnie location used a "Palomar ICON INTENSE PULSED LIGHT (IPL)."² Physician A stated,

The IPL is not a laser and we were advised by the sales representatives and manufacturer that it did not fall under the regulations for Laser medical devices... Since learning of this complaint I have consulted with experienced healthcare counsel and read the Board Declaratory Ruling on Laser Hair Removal and other Board regulations on cosmetic procedures. While I still believe that the IPL is non-ablative and not a laser, I nevertheless have stopped using a medical assistant in any way on the IPL equipment (other than just seeting up the procedure room and getting the patient ready for the procedure).

- 7. On or about June 8, 2015, Board staff interviewed Physician A at the Board's offices. In his interview, Physician A stated that two of his assistants ("Assistant A" and the Respondent) at Practice A's Glen Burnie location performed hair removal and photo-rejuvenation procedures on patients using IPL. Physician A stated that he would always conduct the initial evaluation and physical examination of patients. Once he determined that the IPL procedure was appropriate and with the patient's consent, either he, Assistant A or the Respondent would perform the procedure. When asked to review some of the patient medical records the Board obtained, Physician A confirmed that Assistants A and the Respondent treated those patients using the IPL device.
 - 8. Towards the end of the interview, Physician A stated,

Yes. With the laser versus IPL, it really was confusing to sort through the regulations in the beginning. Because I believe, and I still believe, that IPL is not a laser, non -- it's not ablative. It's nonsurgical in nature. And because of the advice I did get, because I sought the advice of the manufacturer as well as our office managers and community physicians, et cetera, I truly believe that one, it wasn't laser, and two, because many of the procedures I used IPL for, many of the conditions I used IPL for

² Intense Pulsed Light is a technology that uses a broad spectrum of light source to perform various skin treatments including hair removal, photorejuvenation, skin pigmentation and treatment of dermatologic diseases.

- were, I thought, medical in nature rather than cosmetic in nature, I believe I was doing the right thing... But ever since the inquiry opened up, I stopped everything, and I am performing them myself. And you know, I just want to reiterate that this was an honest oversight on my part, not something intentional.
- 9. Board staff interviewed the Respondent at the Board's offices on or about June 17, 2015. The Respondent stated that she is a licensed aesthetician and had been employed at Practice A's Glen Burnie location since 2012. The Respondent confirmed that she performed hair removal and photo-rejuvenation using IPL on Physician A's patients from in or around August 2013 to August 2014. The Respondent stated after August 2014, she was promoted to a leadership position at Practice A and since then, only performed IPL procedures on occasion. According to the Respondent, she had not performed IPL procedures at Practice A since Board staff's unannounced visit in or around May 2015.
- 10. On or about June 17, 2015, Board staff interviewed Assistant A at the Board's offices. Assistant A stated that she had been employed as a medical assistant and performed IPL procedures on Physician A's patients at Practice A's Glen Burnie location since September 2014. Assistant A stated that she stopped performing IPL procedures since Board staff's unannounced visit in or around May 2015.
- 11. During the interviews, both Assistants A and the Respondent were shown patient medical records and both confirmed that they had performed IPL procedures on those patients. They further stated that based on information they received from the manufacturer of the device and from Practice A, they mistakenly thought that they were authorized to perform IPL procedures.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent, who was unlicensed in any health occupations, performed cosmetic medical procedures using IPL at the direction of Practice A, in violation of Health Occ. II § 14-601 and COMAR 10.32.09 *et seq*.

<u>ORDER</u>

Based on the foregoing Findings of Fact and Conclusions of Law, it is, by a majority of the quorum of the Board considering this case:

ORDERED that within SIXTY (60) DAYS of the date of this Consent Order, the Respondent shall pay a monetary fine in the amount of ONE THOUSAND DOLLARS (\$1,000.00), by bank certified check or money order, made payable to the Maryland Board of Physicians, P.O. Box 37217, Baltimore, Maryland 21297; and it is further

ORDERED that this Consent Order is a PUBLIC DOCUMENT pursuant to Md. Code Ann., Gen. Provisions §§ 4-101 *et seq.* (2014).

03/24/2016 Date

Christine A. Farrelly[✓]

Executive Director

Maryland State Board of Physicians

CONSENT

I, Irene Hanzigiannis, acknowledge that I am represented by counsel and have consulted with counsel before entering into this Consent Order. By this Consent and for the sole purpose and no other of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego my opportunity to challenge these allegations. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed after any such hearing.

I sign this Consent Order, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order.

3.9.16 Date

Irene Hanzigiannis

NOTARY

CITY/COUNTY OF MONT COMEC	
I HEREBY CERTIFY that on this	9 day of MARCH,
2015, before me, a Notary Public of the	ne foregoing State and City/County personally
appear Irene Hanzigiannis and made oath in due form of law that signing the foregoing	
Consent Order was her voluntary act and deed.	
AS WITNESSETH my hand and notary seal.	
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ALLEN TAVAREZ NOTARY PUBLIC OF THE STATE OF MARYLAND IN AND FOR MONTGOMERY COUNTY My Commison Expires 08.03.2019	Notary Public (My commission expires: \$\sigma 3 \right)14