

IN THE MATTER OF	*	BEFORE THE MARYLAND
OSCAR M. RAMIREZ, M.D.	*	STATE BOARD OF PHYSICIANS
Respondent.	*	Case Numbers: 2005-0352, 2006-0868 &
		2008-0618
License No. D21826	*	
* * * * *		

## **FINAL DECISION AND ORDER**

### **Procedural History**

Oscar M. Ramirez, M.D. is a board-certified plastic surgeon licensed by the Maryland State Board of Physicians ("Board"). In April, 2009, the Board charged Dr. Ramirez with failing to meet appropriate standards for the delivery for quality medical care, in violation of the Medical Practice Act, Md. Code Ann., Health Occ. § 14-404(a)(22). The Board's charges were based on Dr. Ramirez's performance of lengthy multiple cosmetic surgical procedures in his outpatient office-based setting on two patients,<sup>1</sup> Patient A and Patient B, and on his intra-operative and post-operative management of Patient A's fluids. Dr. Ramirez performed a combination of abdominal and lower body cosmetic surgical procedures in one continuous operation that lasted almost 10 hours on Patient A, a 58-year old female patient. He performed multiple cosmetic facial surgical procedures in one continuous operation lasting over 12 hours on Patient B, a 55-year old male patient. Both patients, who were otherwise healthy, died postoperatively of cardiac arrhythmia following the procedures performed by Dr. Ramirez.

Dr. Ramirez requested and received an evidentiary hearing on August 24, 26 and 27, 2010, at the Office of Administrative Hearings. At that hearing, the evidence included expert testimony from Dr. Ramirez and from Leroy Young, M.D., who is licensed in Missouri, on

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<sup>1</sup> For purposes of confidentiality, the two patients involved in this case are referred to as Patient A and Patient B throughout this Final Decision and Order.

behalf of Dr. Ramirez, and from Coleman Brown, M.D. for the State. In a 50-page Proposed Decision issued on November 17, 2010, Administrative Law Judge (“ALJ”) Stephen J. Nichols found that Dr. Ramirez’s performance of these lengthy multiple plastic surgical procedures on Patients A and B at Esthetique Internationale (“EI”), his outpatient surgical center in Timonium, Maryland, violated standards of quality care. The ALJ found that Dr. Ramirez’s management of Patient A’s fluids was appropriate. The ALJ recommended that Dr. Ramirez’s medical license be revoked.

Dr. Ramirez filed exceptions to the ALJ’s Proposed Decision and the State filed a Response to Dr. Ramirez’s exceptions. Both parties appeared before the Board for an oral exceptions hearing. After considering the entire record in this case, including the pre-hearing motions and record made before the ALJ, and the written and oral exceptions<sup>2</sup> by both parties, the Board now issues its Final Decision and Order.

### **UNDISPUTED EVIDENCE**

#### **1) Dr. Ramirez’s Practice at EI**

The following facts are undisputed: (1) Since 1999, Dr. Ramirez has engaged in the practice of plastic surgery at EI, an outpatient surgical center that included a single operating room, a pre-anesthesia room, and a post-anesthesia care unit equipped to monitor patients overnight; (2) Dr. Ramirez was EI’s sole owner and director; (3) EI is not, and never has been licensed by the State as an ambulatory surgery facility; (4) From 1999 – 2005, the American Association for Accreditation of Ambulatory Surgery Facilities (“AAAASF or Quad A”) issued a certificate annually to EI certifying that it met the standards of a Class A/B/C ambulatory

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<sup>2</sup> The Board gives little weight to the FDA Press Release that Dr. Ramirez attached to his written exceptions. That document, which concerns the withdrawal of a prescription pain medication from the U.S. market at the FDA’s request, is not relevant to the issues before the Board in this decision.

surgery facility where major surgical procedures under general anesthesia are performed; (5) The certifications were based upon on-site inspections by the AAAASF in 1999 and 2002, and on a review of interim self-evaluations by Dr. Ramirez in 2000, 2001, 2003, and 2004; (6) Since 2003, Dr. Ramirez has not held admitting privileges at any Maryland hospital; (7) Dr. Ramirez used a verbal agreement with Joseph Orlando, M.D., another plastic surgeon, to admit any of Dr. Ramirez's patients with postoperative complications to a hospital and be their attending physician; and (8) Dr. Ramirez also had a contract with the American Red Cross to have blood products delivered to EI, though that process would take an hour and a half.

## 2) Patients A and B

It is also undisputed that on February 23, 2005, Dr. Ramirez performed multiple cosmetic surgical procedures at EI on Patient A, consisting of a bilateral thigh circumferential suction-assisted lipectomy (liposuction), a circumferential lower body lift which included an abdominoplasty or tummy tuck, and a ventral hernia repair with mesh. Dr. Ramirez posted this case for 8 hours on the surgical posting sheet. The surgical portion of Patient A's operation took 9 hours and 37 minutes and the total anesthesia time was 10 hours and 27 minutes. Dr. Ramirez kept Patient A overnight in EI, and discharged her home the next day. On February 26, 2005, Patient A's husband awoke to find her not breathing, and called 911. Efforts to resuscitate her failed and she was pronounced dead. A post-mortem examination attributed her death to cardiac arrhythmia.

On September 30, 2004, Dr. Ramirez had also performed multiple cosmetic surgical procedures at EI on Patient B, consisting of an endotemporal midface lift with Bichat's fat pad excision bilateral, a cervicofacial (neck and face) lift, bilateral cheek implants, chin implant, and hair transplantation to bilateral temporal and moustache areas. The surgical portion of Patient B's

operation took 12 hours and 7 minutes, and total anesthesia time was 12 hours and 40 minutes. Patient B went into respiratory and cardiac arrest one hour and 40 minutes after extubation at EI, efforts to resuscitate him failed, and he died there. A post-mortem examination also attributed Patient B's death to cardiac arrhythmia.

3) Guidelines of the American Society of Plastic Surgeons ("ASPS")

Neither Dr. Ramirez nor the State disputed the general practice advisory guidelines on patient safety developed and published by a task force for the American Society of Plastic Surgeons ("ASPS") pertaining to the performance of plastic surgery procedures performed in office-based and ambulatory surgery settings. Both parties referred to the ASPS standards and guidelines in articles admitted into evidence at the administrative hearing. (Resp. Exhs. 9-16; St. Exhs. 22-27) The State and Dr. Ramirez agreed that the guidelines do not by themselves define the standard of care, but both agreed that patient safety was a core principle. The ASPS endorsed certain fundamental practice guidelines: that operating surgeons have hospital privileges; that facilities be licensed by the state or accredited; that the overall duration of procedures performed not exceed 6 hours, and that procedures involving blood loss of 500 cc or greater be performed only where adequate blood and blood components are immediately available.

**FINDINGS OF FACT**

The Board adopts the findings of fact numbered 1-76 proposed by the ALJ. (The ALJ's Proposed Decision of November 17, 2010, is incorporated by reference into this Final Decision and Order and is appended to this Order as Attachment A). The Board adopts the ALJ's discussion and analysis on pages 17-50 of the Proposed Decision, but declines to adopt the ALJ's statement on page 48 of the Proposed Decision that Dr. Ramirez's lack of malpractice insurance indicated bad faith. In addition, the Board modifies the last paragraph on page 30 to clarify that

Dr. Ramirez performed surgery on Patient B in September, 2004, and on Patient A in February, 2005. The Board also corrects a typographical error in Footnote 14 on page 28 of the Proposed Decision, which should read “Health-General § 19-125.”

Dr. Ramirez had no hospital admitting privileges or written transfer agreement with any hospital and kept patients overnight at EI, which was not certified as an ambulatory surgery facility by the AAAASF. EI was not licensed or regulated by the State. Blood products were not available for an hour and a half at EI. Dr. Ramirez performed multiple types of cosmetic surgical procedures in one continuous operation on Patients A and B, resulting in very lengthy operating times for both patients. He failed to properly weigh the presumed benefits of performing the extensive combination of procedures for 10 and 12 hours against the potential risks that he created by doing so at EI. His lack of judgment in these cases jeopardized the safety of his patients, created unacceptable risks of complications and violated the standard of quality care. This determination would be the same no matter what the outcome with respect to the two patients.

## **CONSIDERATION OF EXCEPTIONS**

### **I. STATUS OF EI**

#### **1) AAAASF Accreditation Requirements**

The ALJ found that EI was an office-based surgical facility and not an ambulatory surgery facility for purposes of the standard of care analysis in this case. The ALJ also found that despite its certification by the AAAASF, EI failed to meet the organization’s standards for accreditation as an ambulatory surgery facility for 2004 and 2005. The Board agrees. Because EI was neither a licensed ambulatory surgery facility nor a properly certified AAAASF facility, Dr. Ramirez violated the standard of care by performing these extensive procedures there.

Throughout his exceptions, Dr. Ramirez asserts that the ALJ's proposed findings and conclusions are not supported by the evidence presented at the hearing. This argument is incorrect. Dr. Ramirez testified that EI was an ambulatory surgery facility because it was accredited by the AAAASF. (T. 339) The AAAASF standards checklist presented by Dr. Ramirez at the hearing, however, showed that accreditation as an A, B and C facility required a facility to meet every A, B and C standard listed by the AAAASF. (Resp. Exh. 7) One of these standards required "a written transfer agreement with a local accredited or acute care hospital which is approved by the [hospital's] medical staff or the surgeon has privileges to admit patients to such a hospital after having surgery in the facility." *Id.*

Dr. Ramirez, however, had given up his hospital privileges in 2003 because he decided to stop carrying medical malpractice insurance then. (T. 272) He proffered no evidence of a written transfer agreement with any hospital in response to questions on the subject at the hearing. He stated only that he used a verbal agreement with Joseph Orlando, M.D. to admit his patients to Good Samaritan Hospital if needed, and had used this agreement on a few occasions to do so. (T. 272-74). According to Dr. Ramirez, the agreement involved calling Dr. Orlando and then calling an ambulance to transfer patients to the hospital where Dr. Orlando would admit them. (T. 347, 355, 358) Dr. Orlando admitted that their agreement was not in writing, but "was actually a handshake agreement." (T. 390-91)

Dr. Ramirez also stated that in the event of a real emergency, he would call an ambulance and transfer the patient to the nearest hospital. (T. 358-59) The complaint received by the Board showed that in actual emergency situations, Dr. Ramirez did not even utilize his verbal agreement with Dr. Orlando but referred patients to another hospital where he did not have either privileges or a written transfer agreement. (St. Exh. 1, OR 10001-2) Based on the testimonial

and documentary evidence, the Board finds that Dr. Ramirez failed to meet either prong of the AAAASF standard because he had neither hospital admitting privileges nor a written transfer agreement with a local acute care hospital. Dr. Ramirez thus failed to meet one of the critical AAAASF standards, because he could not offer his patients seamless admission to a hospital in an emergency.

At the hearing, Dr. Ramirez also relied on certificates presented to EI by AAAASF from 1999 through 2005 documenting that EI met the standards for accreditation as an ambulatory surgery facility. (Resp. Exh. 8) He testified that the certificates were based upon on-site inspections and evaluations done by the AAAASF and interim self-evaluations by himself. (Resp. Exhs. 7; T. 267-68, 339) He identified a document entitled “Standards and Checklist for accreditation of ambulatory surgery facilities” as the Checklist that applied during on-site evaluations of EI by the AAAASF and the one he used for his own interim self-evaluations, including his self-evaluations in 2003 and 2004. (T. 267-69; Resp. Exh. 7)

Dr. Ramirez now contradicts his testimony by asserting for the first time in his exceptions that this Checklist was not the one used by the AAAASF to accredit EI prior to 2005, and implies that hospital privileges or a written transfer agreement with a hospital were not AAAASF requirements during that time. The Board rejects his argument as totally inconsistent with his testimony at the hearing, inconsistent with the AAAASF accreditation standards in effect from 1999-2005, and inconsistent with the specific ASPS patient safety principle that operating surgeons have hospital privileges. The Board also agrees with the ALJ’s inference that Dr. Ramirez failed to disclose to the AAAASF in his 2003 and 2004 self-evaluations that he no longer had hospital admitting privileges and that EI did not have a written transfer agreement with a local acute care hospital. Thus, EI did not meet either of these two requisite AAAASF

standards, was not entitled to certification as an ambulatory surgery facility for 2004 and 2005, and was improperly certified as such. The mere label of AAAASF certification conferred on EI, therefore, is meaningless for purposes of determining the standard of care in this case.

Dr. Ramirez also misconstrues the AAAASF standards on personnel, which require operating physicians to show that they hold, or demonstrate that they have held, hospital privileges. Dr. Ramirez suggests for the first time in his exceptions that if he had such privileges at some point in the past, he did not need them in the present. The standards, however, mandate that physicians have privileges at the time they perform the procedures, not simply at some time in the past. The fact that he had hospital privileges before 2003 did not exempt Dr. Ramirez from that requirement at the time of his self-evaluations in 2003 and 2004. His argument is illogical.

The Board rejects Dr. Ramirez's exceptions arguments that EI was accredited. The Board also agrees with the ALJ that Dr. Ramirez had no written transfer agreement with a hospital. In addition, the Board rejects Dr. Ramirez's contention that the ALJ erroneously admitted evidence of his lack of medical malpractice insurance and his civil lawsuit and settlement in Patient A's case. Dr. Ramirez's decision to stop carrying malpractice insurance precluded his obtaining hospital privileges. This evidence was relevant to the ultimate safety of his patients, and was not unduly prejudicial. Dr. Ramirez's settlement with Patient A's estate is also related to his lack of malpractice insurance, which, again, is related to his lack of hospital privileges, his lack of genuine AAAASF certification, and his consequent ability to care for patients in emergencies. The ALJ correctly admitted this evidence.

Dr. Ramirez's failure to adhere to the AAAASF standards also undermines Dr. Young's opinion that EI was an ambulatory surgery center just because of its label of AAAASF certification. (T. 416-17, 480) Dr. Young testified that the AAAASF had very strict requirements



to ensure patient safety and quality control, including a requirement that plastic surgeons have hospital privileges. (T. 416-17) He also opined, however, that plastic surgeons could just have an agreement with someone who has privileges. (T. 416) This testimony was contrary to the AAAASF standards. He conceded on cross-examination that he did not know the standards required a written transfer agreement with a local accredited or acute care hospital. (T. 480) Dr. Young's opinion regarding the mandatory AAAASF standards is unpersuasive and the ALJ correctly rejected it. So does the Board.

2) The Maryland Health Resources Planning Commission's Reference to EI

The incidental reference to EI as a single operating room freestanding ambulatory surgery facility in a September, 1999 letter from the Director of the Maryland Health Resources Planning Commission to Dr. Ramirez is similarly irrelevant for purposes of the standard of care analysis in this case. (Resp. Exh. 17) The Commission's letter simply responded to Dr. Ramirez's prior request for a determination of non-coverage under Certificate of Need, acknowledged the relocation of Dr. Ramirez's facility and its name change to EI, and clarified that EI was exempt from Certificate of Need requirements. The letter was not intended to nor did it confer licensure status on EI because the licensure requirements for an ambulatory surgery facility are distinct from the requirements for a Certificate of Need. *See* Md. Code Ann., Health-Gen. § 19-101(b)(1996 & Supp. 1998); Md. Code Ann., Health-Gen. § 19-117(1)(1996).<sup>3</sup>

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<sup>3</sup> At the time of the Commission's letter to Dr. Ramirez in 1999, Maryland law defined an ambulatory surgical facility as any facility with two or more operating rooms that sought reimbursement from payors and provided surgical services to patients who did not require overnight hospitalization. Md. Code Ann., Health-Gen. § 19-101(b) (1996 & Supp. 1998) (renumbered as Health-Gen. § 19-114 and amended by Acts 1999, ch. 702, §§ 2, 5, effective Oct. 1, 1999). A certificate of need is required before an ambulatory surgery facility:

(1) Offers any health service:

(i) Through a health care facility;

(ii) In space leased from a health care facility; or

(iii) In space on land leased from a health care facility . . . . Md. Code Ann., Health-Gen. § 19-117(1)(1996) (renumbered as Health-Gen. § 19-125 and amended by Acts 1999, ch.702, § 2, effective Oct. 1, 1999.

It is undisputed that EI's one operating room was used exclusively by Dr. Ramirez, that he kept patients overnight, that his office did not receive a technical or facility fee and that he sought no reimbursement from third-party payors. Md. Code Ann., Health-Gen. § 19-3B-01(b)(iv) (2005).<sup>4</sup> His office was thus not an ambulatory surgery facility eligible for State licensure. The Commission's incidental and mistaken use of that term in no way establishes that EI was a freestanding ambulatory surgery facility in 1999, 2004 or 2005. Dr. Ramirez's arguments to the contrary are not supported by the evidence.

Another AAAASF standard requires that a facility comply with all pertinent state laws and regulations if overnight stays are permitted. (Resp. Exh. 7) State law prohibits overnight stays. Md. Code Ann., Health-Gen. § 19-3B-01(b)(1). As the EI Director, Dr. Ramirez attested that EI met all governmental regulations that were stricter than the AAAASF standards. *Id.* That was not the case with Patient A, because Dr. Ramirez began her lengthy procedures around 10 a.m. on February 23, 2005, and discharged her around 1 p.m. the next day after an overnight stay of longer than 24 hours. (T. 342) In his deposition in Patient A's malpractice case, Dr. Ramirez admitted that State law prohibited overnight stays greater than 24 hours and that if procedures required a stay exceeding that time frame, they should be performed in a hospital. (St. Exh. 28, T. 61-62) Dr. Ramirez failed to comply with either with the AAAASF standard or State law. The ALJ's application of Maryland licensure law to ambulatory surgery facilities was correct.

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<sup>4</sup> In 2005, Maryland law similarly defined an ambulatory surgery facility as an entity that sought reimbursement from payors and provided surgical services to patients who did not require overnight hospitalization. Md. Code Ann., Health-Gen. § 19-3B-01(b)(1)(i), (ii) and (iii) (2005). This definition of an ambulatory surgery facility specifically excluded "the office of a group of health care practitioners with not more than one operating room if:

1. The office does not receive a technical or facility fee; and
2. The operating room is used exclusively by members of the group practice for patients of the group practice . . ."

*Id.* § 19-3B-01(b)(iv).

### 3) Distinctions Between Office-Based Surgical Centers and Ambulatory Surgery Facilities

In distinguishing surgical procedures conducted in an office-based setting from those conducted in ambulatory surgery facilities, the expert witnesses for the State and Dr. Ramirez agreed that office-based practices typically have less resources, and less control over events, than ambulatory surgery facilities. Dr. Brown established that, in an ambulatory surgery facility, a director or someone other than the operating surgeon would exercise independent decision-making control. (T. 209) Dr. Brown also testified that, on the other hand, an ambulatory surgery facility would provide a level of safety similar to that provided in a hospital because more practicing multi-specialty physicians would be involved. (T. 147, 156) Dr. Young admitted that office based facilities have less resources, and are smaller, with less control over things and no real certification process, whereas an ambulatory surgery facility has to meet the standards of a certifying organization like the AAAASF or be certified by the State. (T. 415, 478, 489-90) Based on its own knowledge and expertise, the Board agrees with these assessments.

Dr. Young testified that both his own surgical facility in Missouri and EI were ambulatory surgical facilities. Based on Dr. Young's description of his facility, however, EI is not remotely comparable to Dr. Young's ambulatory surgery facility, and his testimony only highlighted the significant differences between them. Dr. Young's facility is affiliated with a hospital, has four operating rooms, is licensed by the state of Missouri, and is inspected by the State and the Joint Commission. (T. 456-57, 476-77, 511) Unlike Dr. Ramirez, Dr. Young has hospital admission privileges. (T. 476-77) Dr. Young also performs operations jointly with another board certified plastic surgeon to decrease the duration of procedures performed. (T. 431)

The evidence contradicts Dr. Ramirez's challenges to the ALJ's findings on this issue in his exceptions. EI did not meet AAAASF certification standards, nor was it licensed as an ambulatory surgery facility by the State of Maryland. Only Dr. Ramirez exercised control over the decision-making process and surgical posting schedule at EI, because he was the sole owner, director and board-certified plastic surgeon at the center. The Board rejects his exceptions to the ALJ's findings and finds that EI was an office-based outpatient surgical practice, not an ambulatory surgical facility.

## **II. THE STANDARD OF QUALITY CARE REQUIREMENTS**

In his exceptions, Dr. Ramirez concedes that the standard of care is rarely determined by artificial labels. The Board agrees. Whether Dr. Ramirez violated appropriate standards of care does not turn on the label of AAAASF certification, which was shown to have been maintained under false pretences. Dr. Ramirez however, then relies completely on this label to assert that he met appropriate standards of care because EI was accredited by the AAAASF. He thus relies completely on the label of AAAASF certification. The Board rejects his self-contradictory arguments.

Similarly, Dr. Ramirez's technical surgical skills, credentials and qualifications are not implicated in the standard of care analysis in this case. Rather, the critical concerns are Dr. Ramirez's judgment in agreeing to perform this particular combination of procedures on Patients A and B for such an excessive length of time, given the actual capabilities of EI with respect to ensuring the safety of both patients.

### **1) EI's Capabilities**

As detailed in Part I *supra*, EI failed to meet the actual AAAASF accreditation requirements. EI was not, therefore, an ambulatory surgery facility within the meaning of either

the AAAASF requirements or the requirements of State law. The Board agrees with Dr. Brown's testimony that Dr. Ramirez's lack of hospital privileges limited Dr. Ramirez's ability to perform certain procedures safely at EI. (T. 70-73) Dr. Ramirez's failure to limit his surgical procedures to those that were within EI's capabilities, compromised patient safety.

Dr. Ramirez also ignored the ASPS safety guideline that blood components should be immediately available if anticipated blood loss from operative procedures was greater than 500 cc. Dr. Ramirez testified that he had a contract with the Red Cross for blood products to be delivered to EI within an hour and a half. (T. 354-55) It is manifest that EI's capability did not comport with this ASPS guideline. The undisputed evidence from Patient's A's anesthesia record showed that she lost 800 cc of blood during the procedures performed by Dr. Ramirez, an amount that Dr. Ramirez failed to anticipate and that well exceeded 500 cc. (St. Exh. 5, OR 10710)

After Patient A's operation, Dr. Ramirez wrote in his operative note that her "estimated (actual) blood loss was minimal." (St. Exh. 5, OR 10697) He conceded during cross-examination that 800 cc was not minimal. (T. 348) Dr. Brown and Dr. Young also agreed that 800 cc was not minimal. (T. 201, 474) Dr. Brown stated that Patient A's anticipated blood loss could have been expected to be greater than 500 cc given the scope of her procedures, and Dr. Young also admitted that it would normally total between 800 to 1040 cc. (T. 177, 497-98) Dr. Young was unaware if EI had adequate blood components immediately available. He did opine that a wait of an hour and a half would still meet the ASPS guideline. (T. 510) The Board rejects Dr. Young's opinion on this issue as illogical, contrary to the plain meaning of the guideline and incompatible with patient safety. Because of the extent of the procedures that Dr. Ramirez agreed to perform on Patient A, and EI's limited ability to obtain blood products immediately, the Board also finds

that he misjudged and minimized not only her blood loss but the potential risks to the patient. His exceptions have no merit.

According to Dr. Brown, the multiple number, type and combination of procedures that Dr. Ramirez performed on Patient A in an office-based surgical setting like EI, together with the 10 hour time frame that it took him to complete them, was excessive, increased the risk of an adverse outcome, and violated the standard of care. (T. 74-83) The Board agrees. Dr. Brown opined that surgical procedures in this setting are best performed within a 6-hour window and if longer than that, the standard of care requires that such procedures be performed in a hospital because hospitals have more personnel, more oversight and more intense monitoring. (T. 82, 175-76, 179) In his own practice, Dr. Brown testified that he does not perform such a combination of procedures in an outpatient setting. (T. 178)

Dr. Brown agreed with Dr. Young that duration alone is not the only relevant factor, and emphasized the importance of also taking into account the type of procedures involved, which in the case of Patient A's lower body lift included not just an anterior abdominoplasty or tummy tuck, but the simultaneous excision of excess skin and fatty tissue around to the upper buttocks and lower back. (T. 74-75, 84) In Dr. Brown's view, the circumferential liposuction of the thighs (front, sides and posterior thigh liposuction) and even the anterior abdominoplasty were procedures that could safely have been combined for Patient A and therefore performed within a time frame consistent with the standard of care. (T. 79, 98) The Board concurs with Dr. Brown's opinion that Dr. Ramirez's decision to simultaneously perform a lower body lift and thigh lift created an unacceptable risk for the patient of fluid shifts and blood loss, because of the length of the combined planned procedures. (T. 98-99).

Dr. Brown also testified that the duration and the particular type and combination of procedures that Dr. Ramirez performed on Patient B violated the standard of care. (T. 116) The five procedures consisted of an endotemporal mid-facelift to elevate the mid-face; a face and neck lift to rejuvenate the face; bilateral cheek implants; a chin implant inserted either through the mouth or under the jawline to augment the chin; and hair transplantation to bilateral temporal and moustache areas, which required Dr. Ramirez to take hair follicles or groups of hair follicles from one area and place them in the temples in front of the hairline and mustache areas of the upper lip. (T. 113-14) Patients B's first four procedures took about 8 hours and the hair transplant took another 4 hours. (T. 461)

Dr. Brown opined that Dr. Ramirez violated the standard of care by performing these multiple surgical procedures on Patient B combined in one continuous operation that took over 12 hours in this outpatient setting. (T. 117-18) The Board agrees with Dr. Brown. In his expert report, Dr. Young revealed that he had performed similar facial rejuvenation procedures for that length of time, but admitted that he did so in a hospital. (Resp. Exh. 3).

Dr. Ramirez acceded to Patient A's wishes to perform her multiple procedures all at once rather than stage them at different times because she was busy and wanted to look good for her son's wedding. (T. 76) Patient B simply wanted to have all five procedures done as soon as possible with the first available opening in Dr. Ramirez's schedule. (T. 115) For both patients, disclaimers in Dr. Ramirez's operative notes acknowledged that the lengthy duration of the procedures would increase the risks to the patients. (St. Exh. 5, OR 10693; St. Exh. 14, OR 1101) Dr. Brown opined that patient preferences as to scheduling and best aesthetic outcome should play only a minor role and should not dictate the surgeon's decisions regarding the safety and numbers of procedures performed. (T. 77, 98, 172) Instead, the surgeon should choose an

appropriate and safe combination for the patient's best outcome so that the duration does not exceed acceptable safety standards. (T. 116-17) Dr. Brown also testified that Patient B's procedures could easily be staged, and disagreed with Dr. Young and Dr. Ramirez that the risks of staging them at different times outweighed the benefits of doing them all at once. (T. 118-19) The Board, as did the ALJ, credits Dr. Brown's testimony in this respect.

## 2) Expert Testimony

All three experts were qualified to testify. All are board-certified reputable plastic surgeons who routinely perform cosmetic surgery procedures. The Board declines to give less weight to Dr. Brown's testimony because his experience was less extensive than Dr. Young or Dr. Ramirez. Dr. Brown's qualifications meet the standard for providing an expert opinion, and Dr. Ramirez did not argue otherwise at the hearing. The Board's evaluation of the respective testimony of each expert is based on the logic, credibility and persuasiveness of their opinions as it relates to the totality of the evidence presented at the hearing. Dr. Brown's opinion was based on his practice, training, experience and his review of the medical records and ASPS literature. Using its own expertise, the Board agrees that Dr. Brown's opinion accurately reflects the standard of quality care on the combination and duration of the procedures performed by Dr. Ramirez. The Board rejects Dr. Ramirez's exceptions to the contrary.

Dr. Brown testified correctly that ambulatory surgery facilities in Maryland would not allow a surgeon to post the types of procedures that Dr. Ramirez performed on Patient A and B because of the duration and the need for an overnight stay. (T. 206-08) It is obvious from the context of Dr. Brown's testimony that he was referring to Maryland-licensed ambulatory surgery facilities which prohibit overnight stays and the performance of procedures of this duration. The Board rejects Dr. Ramirez's mischaracterization of Dr. Brown's testimony in his exceptions and



his attempt to portray EI as an ambulatory surgery facility based solely on the reference in the 1999 letter from the Health Resources Planning Commission.

Dr. Young's opinion that Dr. Ramirez met the standard of care is not persuasive because it was founded on his mistaken assumptions that EI was properly accredited as an ambulatory surgery facility and that Dr. Ramirez complied with the strict safety requirements of the accrediting association. Based on the evidence, that is not the case. Dr. Ramirez not only failed to meet the AAAASF's critical requirements for certification, but he ignored the ASPS guidelines on blood availability and duration of procedures. Dr. Young's testimony that Dr. Ramirez's judgment was reasonable or within the standard of care does not hold up in the face of EI's obvious deficiencies. Dr. Brown's opinion is more logical and persuasive because he correctly identified EI's serious limitations and the unacceptable risks that Dr. Ramirez created for both patients by performing this combination of procedures over such a lengthy time frame.

EI was certainly not as safe as a hospital, despite Dr. Ramirez's testimony to that effect. EI was incapable of providing a safety net or an array of support comparable to a hospital for patients undergoing the long-term procedures performed by Dr. Ramirez. No other physicians, anesthesiologists or staff oversaw the choice of an appropriate combination and duration of procedures because no one other than Dr. Ramirez and his immediate operative team participated in the decision-making process before or during the operations. Dr. Ramirez's non-existent hospital privileges meant that, in an emergency, adequate and timely hospital support services were not accessible. The reality of EI's limitations, which were within Dr. Ramirez's exclusive control, seriously undermined patient safety. His exceptions have no merit, and the Board rejects them.

## **CONCLUSIONS OF LAW**

Dr. Ramirez violated standards of quality care by performing multiple plastic surgery procedures on each patient as one continuous lengthy operation in an outpatient surgical setting lacking adequate resources to deal with complications that could reasonably be expected to arise. In so doing, Dr. Ramirez endangered both patients, in violation of Md. Code Ann., Health Occ. § 14-404(a)(22).

## **SANCTION**

In September, 2004, Dr. Ramirez performed multiple cosmetic surgical procedures on Patient B in one continuous operation lasting over 12 hours at EI. Patient B died shortly thereafter. In February, 2005, despite this experience, Dr. Ramirez again scheduled and performed another set of multiple surgical procedures in one continuous operation lasting almost 10 hours on Patient A. This patient also died 3 days later. When he performed these procedures, Dr. Ramirez knew that he did not have hospital privileges or a written transfer agreement with a hospital. EI's label of accreditation was issued in error and was based on Dr. Ramirez's omission of critical information during the AAAASF certification process.

Dr. Ramirez was aware of the ASPS guidelines that the overall duration of procedures performed should not exceed 6 hours, and that procedures involving blood loss of 500 cc or greater should be performed only where adequate blood components are immediately available. He ignored these safety guidelines. Patient A's anticipated blood loss was 800 cc, yet Dr. Ramirez performed her multiple procedures in his outpatient office setting knowing that no blood products would be available for an hour and a half. He allowed his patients' wishes and desire for convenience to dictate the scope of the procedures despite the increased duration and the unacceptable risks involved. He exposed his patients to unnecessary harm, not once, but

twice in a 6-month period. The Board has concerns about Dr. Ramirez's insistence that EI provided exactly the same safety environment as a hospital. Dr. Ramirez has demonstrated no insight into the limitations of EI or the dangers posed by his flawed judgment and repeated violations of the standard of care. His continued practice would pose a danger to Maryland patients. The Board will revoke his medical license.

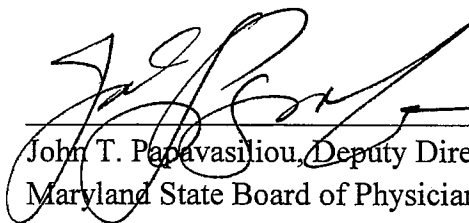
**ORDER**

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 15<sup>th</sup> day of July, 2011, by a majority of the quorum of the Board:

**ORDERED** that the medical license of Oscar M. Ramirez, M.D., be **REVOKED**; and it is further

**ORDERED** that this is a Final Order and as such is a **PUBLIC** document pursuant to Md. State Gov't Code Ann. §§ 10-611 et seq. (2009 Repl. Vol.)

7/15/2011  
Date

  
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John T. Papavasiliou, Deputy Director  
Maryland State Board of Physicians

### **NOTICE OF RIGHT TO APPEAL**

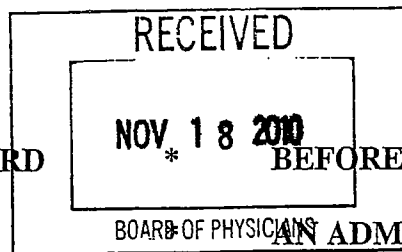
Pursuant to Md. Health Occ. Code Ann. § 14-408, Dr. Ramirez has the right to take a direct judicial appeal. Any appeal shall be filed within thirty (30) days from the mailing of this Final Decision and Order and shall be made as provided for judicial review of a final decision in the Maryland Administrative Procedure Act, Md. State Gov't Code Ann. § 10-222 and Title 7, Chapter 200 of the Maryland Rules of Procedure.

If Dr. Ramirez files an appeal, the Board is a party and should be served with the court's process at the following address:

**Maryland State Board of Physicians  
c/o Yemisi Koya, Esq., Chief, Compliance  
4201 Patterson Avenue  
Baltimore, Maryland 21215**

The Administrative Prosecutor is no longer a party to this case and need not be served or copied.

MARYLAND STATE BOARD  
OF PHYSICIANS



BEFORE STEPHEN J. NICHOLS,  
AN ADMINISTRATIVE LAW JUDGE

v.  
OSCAR M. RAMIREZ, M.D.,  
RESPONDENT

\* OF THE MARYLAND OFFICE OF  
\* ADMINISTRATIVE HEARINGS  
\*  
\* OAH CASE NO.: DHMH-SBP-71-10-06233

\* \* \* \* \*

**PROPOSED DECISION**

STATEMENT OF THE CASE  
ISSUES  
SUMMARY OF THE EVIDENCE  
FINDINGS OF FACT  
DISCUSSION  
CONCLUSIONS OF LAW  
PROPOSED DISPOSITION  
NOTICE OF RIGHT TO FILE EXCEPTIONS

**STATEMENT OF THE CASE**

On April 1, 2009, the Maryland State Board of Physicians (Board) issued charges against Oscar M. Ramirez, M.D. (Respondent) for failure to meet appropriate standards for the delivery of quality medical care in violation of the Medical Practice Act. Md. Code Ann., Health Occ. § 14-404(a)(22) (Supp. 2010). The Board forwarded the charges to the Office of the Attorney General for prosecution.

I held a hearing over three days starting on Tuesday, August 24, 2010, and continuing Thursday, August 26, 2010 through Friday, August 27, 2010, at the Office of Administrative Hearings (OAH), 11101 Gilroy Road, Hunt Valley, Maryland. Md. Code Ann., Health Occ. § 14-405(a) (2009). Victoria H. Pepper, Assistant Attorney General and administrative prosecutor,

represented the State of Maryland (State). M. Natalie McSherry, Esquire, represented the Respondent.

Procedure in this case is governed by the contested case provisions of the Administrative Procedure Act, the Rules of Procedure for the Board, and the OAH Rules of Procedure. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2009 & Supp. 2010); Code of Maryland Regulations (COMAR) 10.32.02; COMAR 28.02.01.

### ISSUES

(1) Whether the Respondent violated appropriate standards of care for the delivery of quality medical care to Patient A in violation of section 14-404(a)(22) of the Health Occupations Article of the Annotated Code of Maryland by conducting Patient A's multiple plastic surgery procedures as a continuous operation lasting over nine hours in an outpatient office-based setting and/or failed to manage her fluids (input and output) appropriately?

(2) Whether the Respondent violated appropriate standards of care for the delivery of quality medical care to Patient B in violation of section 14-404(a)(22) of the Health Occupations Article by conducting Patient B's multiple plastic surgery procedures as a continuous operation lasting over twelve hours in an outpatient office-based setting?

(3) If the preponderance of the evidence establishes any or all of the above prohibited conduct, what sanction(s) should be imposed on the Respondent's license to practice medicine?

## SUMMARY OF THE EVIDENCE

### Exhibits

The following exhibits were admitted on behalf of the Board:

- Bd. Ex. 1. November 10, 2004 letter to Chair, Board of Physicians from President of the Medical Staff, St. Joseph Medical Center with attachment (Bates number: OR 10001 – 10003)
- Bd. Ex. 2. Complaint *Michael Hannan et al. v. Oscar Ramirez et al.* (OR 10004 – 10014)
- Bd. Ex. 3. July 18, 2006 letter from Board staff to Respondent
- Bd. Ex. 4. July 24, 2006 letter from Respondent to Board staff with attachments and an Addendum to Summary, dated July 13, 2008 (OR 10227 – 10250)
- Bd. Ex. 5. Respondent's medical records – Patient A (OR 10689 – 10755)
- Bd. Ex. 6. Patient A records from Metropolitan Medical Associates (OR 10792 -10901)
- Bd. Ex. 7. Patient A records from Howard J. Hoffberg, M.D. (OR 10902 – 10967)
- Bd. Ex. 8. Baltimore County Police Incident Report – Patient A (OR 10990 – 10997)
- Bd. Ex. 9. Baltimore County Emergency Medical Service Report – Patient A (OR 10999 – 11000)
- Bd. Ex. 10. Report of Post-Mortem Examination – Patient A (OR 10968 – 10988)
- Bd. Ex. 11. Death Certificate – Patient A (OR 10989)
- Bd. Ex. 12. March 3, 2009 correspondence to Board staff from Philip C. Federico, Esquire, regarding Respondent's settlement with Patient A's estate
- Bd. Ex. 13. September 25, 2009 Order – Circuit Court for Baltimore County
- Bd. Ex. 14. Respondent's medical records – Patient B (OR 11002 – 11092)
- Bd. Ex. 15. Baltimore County Fire Department records – Patient B (OR 11166 – 11168)
- Bd. Ex. 16. Baltimore County Police Department records – Patient B (OR 11132 – 11165)
- Bd. Ex. 17. Report of Post-Mortem Examination – Patient B (OR 11093 – 11130)
- Bd. Ex. 18. Death Certificate – Patient B (OR 11131)
- Bd. Ex. 19. *Curriculum Vitae* – C. Coleman Brown, M.D.
- Bd. Ex. 20. Peer Review Report – C. Coleman Brown, M.D.
- Bd. Ex. 21. Charges Under the Maryland Medical Practice Act
- Bd. Ex. 22. Gold, B.S. *et al.*, Unanticipated Admission to the Hospital Following Ambulatory Surgery, *Journal of the American Medical Association*, 262:21, 1989
- Bd. Ex. 23. Horton, J.B. *et al.*, Patient Safety in the Office-Based Setting, *Plastic and Reconstructive Surgery*, 61e: 80e, 2006
- Bd. Ex. 24. Rodrich, R.J. *et al.*, Safety of Outpatient Surgery: Is Mandatory Accreditation of Outpatient Surgery Centers Enough?, *Plastic and Reconstructive Surgery*, 107:189, 2001
- Bd. Ex. 25. Rodrich, R.J., *et al.*, Patient Safety First in Plastic Surgery, *Plastic and Reconstructive Surgery*, 114:201, 2004
- Bd. Ex. 26. Iverson, R.E., *et al.*, Patient Safety in Office-Based Surgery Facilities: 1. Procedures in the Office-Based Surgery Setting, *Plastic and Reconstructive Surgery*, 110:1337, 2002

- Bd. Ex. 27. Fogarty, B.J., *et al.*, Complications of long operations; a prospective study of morbidity associated with prolonged operative time (>6h), *British Journal of Plastic Surgery*, 52:33, 1999
- Bd. Ex. 28. Deposition Transcript: Oscar Ramierez, M.D.
- Bd. Ex. 29. Fax Transmittal to Heather McLaughler from Barbara Fagan consisting of thirteen pages, dated March 31, 2009

The following exhibits were admitted on behalf of the Respondent:

- R. Ex. 1. *Curriculum Vitae* – The Respondent
- R. Ex. 2. *Curriculum Vitae* – Leroy Young, M.D.
- R. Ex. 3. Report of Leroy Young, M.D.
- R. Ex. 4. Transcript of Deposition of Anthony M. Zacharek, M.D. in *Hannan v. Ramirez, et al.*, Circuit Court for Baltimore County Case No. 03-C-06-0053-60 MM – dated December 12, 2006
- R. Ex. 5. Transcript of deposition of Charles R. Volpe, M.D. in *Hannan v. Ramirez, et al.* Circuit Court for Baltimore County Case No. 03-C-06-0053-60 MM – dated December 12, 2006
- R. Ex. 6. Transcript of deposition of Amy Swank, CRNA in *Hannan v. Ramirez, et al.* Circuit Court for Baltimore County Case No. 03-C-06 -0053-60 MM – dated October 23, 2007
- R. Ex. 7. AAAASF Standards and Checklist for Accreditation of Ambulatory Surgery Facilities
- R. Ex. 8. AAAASF records relating to certification of Esthetique Internationale
- R. Ex. 9. Morello D.C., Colon, G.A., *et al.*, Patient Safety in Accredited Office Surgical Facilities, *Plastic and Reconstructive Surgery*, 99:1496, 1997
- R. Ex. 10. Byrd H.S., Barton F.E., *et al.*, Safety and Efficacy in an Accredited Outpatient Plastic Surgery Facility: A review of 5316 consecutive cases., *Plastic and Reconstructive Surgery*, 112:636, 2003
- R. Ex. 11. Iverson RE, Lynch DJ *et al.* Patient Safety in office-based surgery facilities: II. Patient selection. *Plastic and Reconstructive Surgery*. 110:1785, 2002. Discussion 1791, 2002
- R. Ex. 12. Iverson R.E., Lynch D.J., *et al.*, Practice Advisory on Liposuction, *Plastic and Reconstructive Surgery*, 113:1478, 2004
- R. Ex. 13. Joint Commission Announces 2007 National Patient Safety Goals for Ambulatory Care and Office Based Surgery, *Plastic Surgical Nursing*, 26:152, 2006
- R. Ex. 14. Rohrich R.J., Parker T.H., *et al.*, The Importance of Advanced Cardiac Life Support Certification in Office Based Surgery, *Plastic and Reconstructive Surgery*, 121: 93e, 2008
- R. Ex. 15. Horton J.B., Janis J.E., Rohrich R.J., MOC-PS CME article: Patient Safety in the Office Based Setting, *Plastic And Reconstructive Surgery*, 122:1, 2008
- R. Ex. 16. Haeck P.C., Swanson J.A., *et al.*, Evidence Based Patient Safety Advisory: Patient assessment and prevention of pulmonary side effects in surgery. Part 1 – Obstructive



sleep apnea and obstructive lung disease, *Plastic and Reconstructive Surgery*, 124: 45s, 2009

R. Ex. 17. Letter from Barclay to Smith – September 28, 1999

### Testimony

The following witnesses testified on behalf of the Board:

C. Coleman Brown, M.D.<sup>1</sup>

Heather McLaughlin, Lead Compliance Analyst, Maryland State Board of Physicians

The Respondent testified on his own behalf and presented the following witnesses:<sup>2</sup>

Joseph Orlando, M.D.

V. Leroy Young, M.D.<sup>3</sup>

### Stipulations

The Board and the Respondent agreed to forty-one written stipulated facts filed in this matter. The material stipulations of fact are incorporated into the Findings of Fact, below.

## **FINDINGS OF FACT**

Having considered all of the evidence presented, I find the following facts by a preponderance of the evidence:

1. The Respondent is board-certified in plastic surgery (general).
2. At all times relevant (February 10, 1978 – September 30, 2009), the Respondent was licensed to practice medicine in the State of Maryland.

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<sup>1</sup> Dr. Brown testified as an expert witness in plastic surgery performed in an outpatient office setting, an outpatient ambulatory surgical center, and a hospital, including preoperative patient assessment, staging and planning plastic surgery procedures, and management of fluid administration.

<sup>2</sup> The Respondent also testified as an expert witness in plastic surgery and aesthetic plastic surgery, including the assessment of patients for plastic surgery and the management of patient fluids during surgery.

<sup>3</sup> Dr. Young testified as an expert witness in surgery, plastic surgery, and patient safety, including the preoperative assessment of plastic surgery patients, staging, and the management of fluids during surgery.

3. Starting in 1999, the Respondent owned and maintained an outpatient surgical center for the practice of plastic surgery, Esthetique Internationale (EI), located at 2219 York Road, Timonium, Maryland. The Respondent was the facility director.
4. EI had two parts, an office for administration and a surgical center. The surgical center was approximately 3000 to 3500 square feet with a single operating room for procedures, a pre-anesthesia room, a Post Anesthesia Care Unit (PACU) (with space for two or three patients), and a cleaning area (comprised of two components, a dirty room and a clean room for gas sterilization). The EI PACU was equipped for the monitoring of patients overnight. Among other equipment, a crash cart and a tracheotomy tray were available.
5. Besides the Respondent, staff at EI included a surgical fellow (a trained plastic surgeon) a Certified Registered Nurse Anesthetist (CRNA), and several certified nurses. All staff at EI had Advanced Cardiac Life Support (ACLS) certification.
6. Adjacent to EI was an apartment (that could be monitored by a nurse) where many patients would elect to stay in after surgery.
7. The Respondent had a contract with the American Red Cross to have blood products, if needed, delivered to EI. After a request for blood products, EI could expect to receive a delivery in about an hour and a half. (Tr. 354-355)
8. In 2003, the Respondent ceased carrying medical malpractice insurance. Since 2003, the Respondent has not held privileges to admit patients at any Maryland hospital.
9. Sometime during (approximately) 2003, the Respondent and Joseph Orlando, M.D., another plastic surgeon, made a verbal agreement that Dr. Orlando would, at the Respondent's request, accept EI patients that may have postoperative difficulties or

complications and admit them to a hospital and be their attending physician. The Respondent had been Dr. Orlando's former associate. At all times relevant, Dr. Orlando had privileges to admit patients at the Good Samaritan Hospital in Baltimore, Maryland. From the time the agreement was made, Dr. Orlando has admitted two EI patients at the Good Samaritan Hospital at the request of the Respondent.

10. At all times relevant (December 20, 1999 – December 20, 2005), EI held a certification issued by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) that it met all of the standards of a Class C ambulatory surgery facility. AAAASF evaluation of a facility is done on an annual basis. The following events took place in the evaluations of EI:

- a. On December 20, 1999, John D. Newkirk, Ph.D., M.D., conducted an initial on-site AAAASF inspection of EI. No areas of deficiency were found in the evaluation.
- b. During 2000, the Respondent submitted a self-evaluation to AAAASF as part of an interim year evaluation. A list of deficiencies resulted from the AAAASF review of the self-evaluation. The Respondent made corrections and forwarded the corrections to the AAAASF. The AAAASF found the corrections to meet the standards of the Association.
- c. During 2001, the Respondent submitted a self-evaluation to AAAASF as part of an interim year evaluation. No areas of deficiency were found by AAAASF in its review of the self-evaluation.
- d. On December 19, 2002, Darab Hormozi, M.D., conducted an on-site re-inspection of EI for the AAAASF. No areas of deficiency were found in the evaluation.
- e. During 2003, the Respondent submitted a self-evaluation to AAAASF as part of an interim year evaluation. No areas of deficiency were found by AAAASF in its review of the self-evaluation.
- f. During 2004, the Respondent submitted a self-evaluation to AAAASF as part of an interim year evaluation. No areas of deficiency were found by

AAAASF in its review of the self-evaluation.

(R. Ex. 8)

11. The AAAASF recognizes several classes of ambulatory surgery facilities depending on what types of anesthesia or sedation are administered to patients for the surgical procedures that may be performed. Class A or Class B facilities may perform procedures that do not require general anesthesia administered by an anesthesiologist or a CRNA.
12. The AAAASF defines a Class C ambulatory surgery facility as a facility that may perform the procedures of a Class A or Class B facility and may perform procedures requiring general anesthesia as described below:

Surgical procedures are performed in the facility with intravenous Propofol, spinal or epidural anesthesia, endotracheal intubation or laryngeal mask airway or inhalation anesthesia (including nitrous oxide), spinal or epidural, administered by an anesthesiologist or Certified Registered Nurse Anesthetist (CRNA).

**The facility must meet every “A”, “B” and “C” standard.**

(R. Ex. 7, fourth page, emphasis added)

13. One of the standards for AAAASF certification of a facility as a Class A, Class B, or Class C ambulatory surgery facility is that “there is a written transfer agreement with a local accredited or licensed acute care hospital which is approved by the [hospital’s] medical staff or the surgeon has privileges to admit patients to such a hospital after having surgery in the facility.” (R. Ex. 7, page 16, emphasis in original)
14. At no time did a written transfer agreement exist between EI and any local acute care hospital.
15. The AAAASF standards for Class B or Class C ambulatory surgery facilities on extended stays reads:

If overnight stays are permitted, the facility is in compliance with all pertinent local and state laws and regulations.

If 23 hour stays are permitted, the facility is in compliance with all pertinent local and state laws and regulations.

(R. Ex. 7, page 13)

16. The Respondent would not accept health insurance payments for the cosmetic surgery he performed at EI. (Tr. 338)
17. EI was never licensed or certified by the State as an ambulatory surgical facility. (Tr. 338)
18. As of February 20, 2009, the Respondent closed EI and relocated to Boca Raton, Florida.

**Patient A**

19. Patient A, a 58 year old female, presented to the Respondent at EI on February 10, 2005 with complaints of excess fat on her waistline, saddle bags, hips and legs, and concerns of excess skin of the upper buttocks, falling buttocks, and lower back, as well as loose skin around her thighs and abdomen. She also wanted to address the excess skin and sagging of her upper arms. (Bd. Ex. 5, OR10753-10754)
20. The Respondent had previously performed a facelift on Patient A.
21. Patient A advised the Respondent that she sought body contouring so that she would look good in her dress for her son's upcoming wedding.
22. According to the Respondent's records, Patient A's height and weight was variously reported to be five feet, four inches and 118 pounds or five feet, three inches and 120 pounds. (Bd. Ex. 5, OR10711, OR10713, OR10715, OR10727)
23. The Respondent noted Patient A's past medical history to be unremarkable except for a

hemi-colectomy,<sup>4</sup> Nissen fundoplication, cervical discetomy and hysterectomy. He noted that Patient A had no history of cardiac or pulmonary problems. (Bd. Ex. 5, OR10753-10754)

24. A Nissen fundoplication is a laparoscopic procedure to prevent chronic severe heartburn.
25. In his February 10, 2005 initial consultation note, the Respondent noted that he told Patient A he would do only her lower body at this time, and would defer contouring of her arms until later. The Respondent “told Patient A we will concentrate in the lower body at this time and deal with the arms in the future . . . [a]rms and lower body cannot be combined.” (Bd. Ex. 5, OR10753)
26. The Respondent noted that Patient A wanted to proceed with the surgery on her lower body in one stage because she could not take time off from her busy schedule. The Respondent documented that, “she was told this is a lengthy surgery with a bit higher risk of complications. In the event of a complication she may need to be transferred to a hospital.” (Bd. Ex. 5, OR10754)
27. In the Consent signed by Patient A, the procedures to be done were described as: U-M Abdominoplasty (Abdominoplasty using U-M technique),<sup>5</sup> Standard Lower Body Lift (surgical procedure to lift the sagging skin on lower body), and Medical Thighplasty (removal, tightening, and lifting of excess skin of medial (inner) thighs & liposuction of entire area). (Bd. Ex. 5, OR10737)

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<sup>4</sup> “[H]emicolectomy ...excision of approximately half of the colon.” *Dorland’s Illustrated Medical Dictionary* 799 (29<sup>th</sup> ed. 2000).

<sup>5</sup> “[A]bdominoplasty ... a surgical procedure for tightening the abdominal muscles.” *Mosby’s Medical Dictionary* 6 (8<sup>th</sup> ed. 2009).

28. The Respondent scheduled Patient A's surgical procedures for February 23, 2005.
29. Patient A was cleared for surgery by Jeffrey Cool, M.D. at Medstar Physicians (her primary care provider) on February 18, 2005. (Bd. Ex. 6, OR10888-10900)
30. Patient A was NPO (i.e. nothing by mouth) from midnight on February 22, 2005 until her surgery on February 23, 2005. (Bd. Ex. 5, OR 10735)
31. Patient A underwent bowel prep with Fleet enema and laxative on February 22, 2005, in preparation for her surgery. (Bd. Ex. 5, OR10735)
32. Patient A's pre-operative assessment was done at EI at 0805 (8:05 a.m.) on February 23, 2005. (Bd. Ex. 5, OR10715) On the pre-operative and day of surgery checklist, Patient A was scheduled for a twenty-three hour stay at EI. (Bd. Ex. 5, OR10725, T. 342)
33. On February 23, 2005, Patient A was placed under anesthesia at approximately 0953 (9:53 a.m.) by Amy Swank, a CRNA. (Bd. Ex. 5, OR10707)
34. The Respondent performed the following multiple surgical procedures on Patient A, assisted by two plastic surgery fellows at EI, Anthony M. Zacharek, M.D., and Charles Volpe, M.D.:
  - a. bilateral thigh circumferential suction assisted lipectomy<sup>6</sup>
  - b. abdominoplasty
  - c. circumferential lower body lift
  - d. ventral hernia repair with mesh
35. At approximately 2008 (8:08 p.m.), after being extubated, Patient A was transferred to the EI PACU for recovery. (Bd. Ex. 5, OR10711)

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<sup>6</sup> "[L]ipectomy ... the excision of a mass of subcutaneous adipose tissue, as from the abdominal wall; called also *adipectomy* ... liposuction." *Dorland's Illustrated Medical Dictionary* 1015 (29<sup>th</sup> ed. 2000) (italics in original).

36. The surgical portion of Patient A's procedures took approximately nine hours and thirty-seven minutes (1023 hours to 2000 hours); total anesthesia time was approximately ten hours and twenty-seven minutes.
37. Patient A's intraoperative period took much longer than the Respondent expected. Because of the length of time, the Respondent kept Patient A in the EI PACU instead of the original plan to have her stay overnight in a nearby apartment. Dr. Zacharek stayed at EI overnight to monitor Patient A's condition.
38. Patient A was kept overnight in the PACU and was discharged at approximately 1300 hours (1:00 p.m.) on February 24, 2005, over 24 hours after her surgery had begun. (Bd. Ex. 5, OR10700)
39. Patient A was noted to require a higher than average level of pain medication. (Bd. Ex. 5, OR10707, OR10700)
40. Because of inclement weather, Patient A was transported to her home by ambulance.
41. Patient A was discharged with a urinary catheter still inserted, a Sequential Compression Device and a subcutaneous pain pump, with local analgesic.
42. During the intraoperative period, Patient A received 6,000 cc of fluids (Ringer's lactate) administered intravenously (IV). (Bd. Ex. 28, OR 10278-10279 (page 77-78))
43. During the intraoperative period, Patient A had 2,100 cc of urine and 800 cc of output from her drains. (Bd. Ex. 28, OR10279 (page 78))
44. During the post-operative period, Patient A received 3,600 cc of fluids (Ringer's lactate) administered IV. (Bd. Ex. 28, OR10279 (page 78))
45. During the post-operative period, Patient A had 2,300 cc of urine and 1,220 cc of output



- from her drains. (Bd. Ex. 5, OR10718-10719)
46. The Respondent ordered that Patient A receive 150 cc of IV fluid per hour during the post-operative period. (Bd. Ex. 5, OR10703)
47. During the post-operative period, Patient A received 200 cc of IV fluid per hour. (Bd. Ex. 5, OR10717-10718)
48. During the intraoperative period and the post-operative period, Patient A did not display any of the clinical signs of excess fluid input.
49. On the evening of February 24, 2005, Patient A's husband reported to EI staff that Patient A was not having any problems and that she was not taking any pain medication. (Bd. Ex. 5, OR10699)
50. At approximately 0710 (7:10 a.m.) on February 26, 2005, Patient A's husband awoke, found that Patient A was not breathing and called 911. Patient A did not respond to attempts to resuscitate her and she was pronounced dead at 0755 (7:55 a.m.).
51. The Office of the Chief Medical Examiner (OCME) conducted a post-mortem examination of Patient A. Her weight was reported by that office at autopsy to be 152 pounds.
52. The OCME reported that her "pulmonary parenchyma was congested and edematous, exuding large amounts of bloody fluid."<sup>7</sup> (Bd. Ex. 10, OR 10970)
53. The OCME certified Patient A's cause of death to be cardiac arrhythmia.

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<sup>7</sup> "[P]arenchyma ...the essential elements of an organ; used in anatomical nomenclature as a general term to designate the functional elements of an organ, as distinguished from its framework, or stroma." *Dorland's Illustrated Medical Dictionary* 1324 (29<sup>th</sup> ed. 2000). "[E]dematous ... pertaining to or affected by edema." *Id.* at 568. "[E]dema ...the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to demonstrable amounts in the subcutaneous tissues." *Id.* at 567.

54. The Respondent entered into a non-confidential settlement agreement with Patient A's estate under the terms of which the Respondent agreed to make monetary payments to Patient A's estate over a period of time beginning December 2008.
55. On September 16, 2009, the Respondent filed for bankruptcy. (Tr. 362)
56. By Order of the Circuit Court of Baltimore County dated September 25, 2009, the agreed settlement amount of \$430,000.00 against the Respondent was reduced to an enforceable judgment.
57. Tumescant fluid consists of a dilute solution of lidocaine and epinephrine which serves as a local anesthetic and reduces surgical blood loss.
58. As part of pre-operative planning, Patient A's blood loss should have been expected to be between 800 cc and 1040 cc calculated as follows:
- a. 200 – 240 cc from a bilateral thigh circumferential suction assisted lipectomy
  - b. 200 – 300 cc from abdominoplasty
  - c. 400 – 500 cc from a circumferential lower body lift

**Patient B**

59. Patient B, a 55 year old male, initially presented to the Respondent at EI on September 14, 2004 for cosmetic surgical facial rejuvenation to improve acne scarring on both his cheeks and decrease the fatty appearance of his cheek and mid-face areas. (Bd. Ex. 14, OR11085)
60. Patient B was eager to have several procedures on his face to improve his aesthetic concerns. Patient B informed the Respondent that he was interested in having his procedures as soon as possible, wanting to take the first opening available on the

- physician's surgical schedule or sooner in the event of any cancellation. (Bd. Ex. 14, OR11004)
61. Patient B did not disclose to the Respondent that he had any history of cardiac, pulmonary problems, or any other risk factors for surgery. (Bd. Ex. 14, OR11005, OR11044)
62. In the Consent signed by Patient B, the procedures to be done were described as: Standard Bichat's fat pad excision (removal of cheek fat pad), lower lid skin excision blepharoplasty (removal of excess skin from lower eyelids), biplanar facelift, Standard Augmentation Genioplasty (placement of a Medpor button chin implant to enlarge chin), implants to enlarge both cheeks, and hair transplant to temporal areas and mustache. (Bd. Ex. 14, OR11054)
63. The Respondent scheduled Patient B's surgical procedures for September 30, 2004.
64. Patient B was cleared for surgery by Dr. Syed Zaidi, a physician in an office other than EI. (Bd. Ex. 14, OR11041-11051) Dr. Zaidi was not Patient B's primary care physician. (Bd. Ex. 14, OR11034)
65. In his operative report, the Respondent documented that, "[t]he patient requested multiple procedures and he understood very well that this will take many hours. Since we were not anticipating significant blood loss from those surgeries, we decided to proceed with this with the understanding that the complication rate might be slightly increased. The patient has been made aware in the event of some complication arises [sic] during or immediately after surgery, he might need to be transferred to the hospital." (Bd. Ex. 14, OR11012)

66. Patient B's pre-operative assessment was done at EI at 0715 (7:15 a.m.) on September 30, 2004. (Bd. Ex. 14, OR11023) On the day of surgery checklist, Patient A was scheduled for a twenty-three hour stay at EI. (Bd. Ex. 14, OR11030, T. 343)
67. On September 30, 2004, Patient B was placed under anesthesia at approximately 0908 (9:08 a.m.) by Amy Swank, C.R.N.A. (Bd. Ex. 14, OR11036)
68. The Respondent performed the following multiple surgical procedures on Patient B, assisted by Dr. Zacharek:
- a. endotemporal midface lift with Bichat's fat pad excision bilateral
  - b. cervicofacial lift<sup>8</sup>
  - c. bilateral cheek implants
  - d. chin implant
  - e. hair transplantation to bilateral temporal and moustache areas
69. Because of the length of time it was taking, the Respondent changed his plan for the operation and did not perform a lower lid skin excision blepharoplasty (removal of excess skin from lower eyelids) on Patient B.
70. At approximately 2155 (9:55 p.m.), after being extubated, Patient B was transferred to the EI PACU for recovery. (Bd. Ex. 14, OR11039)
71. The surgical portion of Patient B's procedures took approximately twelve hours and seven minutes (0923 hours to 2130 hours); total anesthesia time was approximately twelve hours and forty minutes.

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<sup>8</sup> "[C]ervicofacial ... pertaining to the neck and face." *Dorland's Illustrated Medical Dictionary* 325 (29<sup>th</sup> ed. 2000).

72. Approximately one hour and forty minutes after extubation, Patient B went into respiratory and cardiac arrest. (Bd. Ex. 14, OR11005)
73. Resuscitative efforts failed and Patient B expired at approximately 2340 hours (11:40 p.m.) on September 30, 2004.
74. Patient B had a history of blood clots on his legs for which he required Heparin subcutaneous treatment given by himself. This information was provided to the Respondent by the patient's significant other after Patient B died. (Bd. Ex. 14, OR11005)
75. The OCME conducted a post-mortem examination of Patient B and noted, in pertinent part, that "[o]rganized thrombi were identified in the deep of the lower extremities, however, only rare fibrin thrombi were identified in the pulmonary vasculature."<sup>9</sup> (Bd. Ex. 17, OR11100)
76. The OCME certified Patient B's cause of death to be "cardiac arrhythmia immediately following plastic surgery." (Bd. Ex. 17, OR11093)

### DISCUSSION

In a physician disciplinary proceeding, the Medical Practice Act places upon the State the burden of proving its charges by a preponderance of the evidence. Md. Code Ann., Health Occ. § 14-405(b)(2) (2009). The Board has charged the Respondent with violating the following subparagraphs of section 14-404(a) of the Health Occupations Article:

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<sup>9</sup> "[O]rganize ... to provide with an organic structure." *Dorland's Illustrated Medical Dictionary* 1276 (29<sup>th</sup> ed. 2000). "[T]hrombi ... plural of thrombus." *Id.* at 1835. "[T]hrombus ... a stationary blood clot along the wall of a blood vessel, frequently causing vascular obstruction." *Id.* at 1837. "[F]ibrin ... the insoluble protein formed in fibrinogen by the proteolytic action of thrombin during normal clotting of blood." *Id.* at 670. "[V]asculature ... any specific part of the circulatory system." *Id.* at 1935.

(a) Subject to the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of the quorum, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:

. . .

(22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State[.]

Md. Code Ann., Health Occ. § 14-404(a)(22) (Supp. 2010).

There are two complaints regarding the Respondent's delivery of medical and surgical care for Patient A and Patient B. First, the Respondent, it is alleged, conducted multiple plastic surgery procedures on Patient A and Patient B as continuous operations lasting over nine or twelve hours, respectively, in an outpatient office-based setting. Second, the Respondent, it is alleged, failed to manage Patient A's fluids (input and output) appropriately during the intraoperative and post-operative periods. On both grounds, the Board contends that the Respondent breached the standard of qualify medical and surgical care required by section 14-404(a)(22).

#### EXPERTS

C. Coleman Brown, M.D., was called to testify by the Board. Dr. Brown is a physician licensed in Maryland with specialty in plastic and reconstructive surgery. Dr. Brown is in practice as a plastic surgeon and he performs the same type of procedures that the Respondent performed on Patient A and Patient B. His *curriculum vitae* reveals that Dr. Brown has extensive training and experience in plastic and reconstructive surgery. In 2005, Dr. Brown was board certified by the American Board of Plastic Surgery. Dr. Brown lists five publications or book chapters and four scientific presentations on his *curriculum vitae*. (Bd. Ex. 19) He was qualified as an expert witness in plastic surgery performed in an outpatient office setting, an outpatient ambulatory surgical

center, and in a hospital, including preoperative patient assessment, staging and planning plastic surgery procedures, and the management of fluid administration.

In his testimony, Dr. Brown indicated that the multiple procedures the Respondent performed on Patient A and Patient B during continuous lengthy operations violated the required standard of care because EI was an office-based surgery facility. Dr. Brown noted that the Respondent, at the time he performed surgery on Patient A and Patient B, did not have privileges to admit patients at any Maryland hospital. According to Dr. Brown, that limited the Respondent's options as to where these surgeries, as planned, could be performed. An accepted guideline in the profession is that surgical procedures in an outpatient setting are best performed within a six-hour window to help prevent undue complications or other adverse events.<sup>10</sup> Although this duration of an operation, by itself, is not an absolute, Dr. Brown stated that the standard of care was breached because of the type and number of the procedures performed along with the decision to combine those procedures as one operation resulted in lengthy operations. A hospital setting provides a greater array of support than an office-based surgery facility in that other equipment and medical staff are available in the hospital setting to assist with patient care and safety.

Dr. Brown believed that the Respondent performed surgery in an office-based surgery facility. Dr. Brown acknowledged that an ambulatory surgery facility provides a greater safety net than does an office-based surgery facility. Dr. Brown admitted during cross-examination that performing the multiple procedures that the Respondent performed on Patient A and Patient B in a

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<sup>10</sup> According to Dr. Brown, a Task Force set up by the American Society of Plastic Surgeons in the 1990s to study and promote patient safety produced guidelines including a six-hour recommendation to help minimize the risk in plastic surgery procedures.

free-standing ambulatory surgery facility might not be a breach of the standard of care:

BY MS. MC SHERRY:

Q. If [Respondent] had performed the procedures at issue with regard to Patient A and Patient B in a freestanding ambulatory surgery center, would that be within the standard of care, in your opinion?

MS. PEPPER: Same objection.

JUDGE: Overruled.

THE WITNESS: No

BY MS. MC SHERRY:

Q. Why not?

A. Because they would probably not allow you to post that case in a freestanding ambulatory surgical center based on the duration.

Q. Assume that the center allowed you to post it, would it be within the standard of care for a physician to do it?

MS. PEPPER: Objection. That's really hypothetical.

JUDGE: Overruled.

THE WITNESS: I disagree.

BY MS. MC SHERRY:

Q. You disagree – it wasn't a disagree or agree question. It was a, would it be within the standard of care?

A. I still disagree.

Q. That's a "yes" or "no."

A. The problem with the question is that that situation would not arise. You can't assume that they would allow you to post it because that wouldn't happen. They would assess the situation and say that this case should not be performed in this setting. The patient will require an overnight stay of some sort or needs to be in the hospital.

Q. But don't they do overnight stays in ambulatory surgery centers?

A. (Shaking head.)

Q. They don't?

A. No.

Q. Then why do all these articles talk about it?

A. Why do they talk about needing a –

Q. Yeah. They talk about overnight stays in ambulatory surgery centers – the ones you relied on.

A. Well, not the ones here in the State of Maryland.

Q. In the literature you relied on it talks about only doing combined procedures in a hospital or an ambulatory surgery center where you can have an overnight stay, right? Remember that one we read a couple of hours ago?

A. Yes.

Q. So if it can happen in an ambulatory surgery center that has overnight facilities it would be within the standard of care to do Patient A's and Patient B's procedures in such a facility, correct?



A. If such a facility existed.

(Tr. 206 - 208) In his testimony, Dr. Brown also indicted that the Respondent failed to manage Patient A's fluids (input and output) appropriately during her operation.

V. Leroy Young, M.D., was called to testify by the Respondent. Dr. Young is a physician licensed in Missouri with specialties in surgery and plastic surgery. His *curriculum vitae* reveals that Dr. Young has had a long and distinguished medical career, including many years as a Chief of Surgical Services at the Barnes-Jewish West County Hospital in St. Louis, Missouri, Associate Professor, Assistant Professor, and Professor of Surgery (Plastic and Reconstructive) at the Washington University School of Medicine in St. Louis, Missouri. Dr. Young lists two hundred publications, books, or book chapters on his *curriculum vitae*. (R. Ex. 2) In 1978, Dr. Young was board certified by the American Board of Surgery. In 1981, Dr. Young was board certified by the American Board of Plastic Surgery. Dr. Young has been in private practice since 2002 performing mainly cosmetic plastic surgery. He was qualified as an expert witness in surgery, plastic surgery, and patient safety, including the preoperative assessment of plastic surgery patients, staging, and the management of fluids during surgery.

In his current private practice, Dr. Young mainly performs cosmetic plastic surgery and he has performed the same type of procedures that the Respondent performed on Patient A and Patient B. Dr. Young operates almost exclusively in the Bodyaesthetic Plastic Surgery & Skincare Center (Bodyaesthetic), an outpatient surgery facility attached to, and affiliated with, the Barnes-Jewish West County Hospital in Missouri. Bodyaesthetic has four operating rooms. Dr. Young has malpractice insurance and admission privileges at the Barnes-Jewish West County Hospital. Dr. Young describes Bodyaesthetic as an ambulatory surgical center. Bodyaesthetic is licensed or

certified by the State of Missouri as an ambulatory surgical center and inspected from time to time by the State of Missouri and the "Joint Commission."<sup>11</sup>

According to Dr. Young, cosmetic procedures such as those performed by the Respondent on Patient A and Patient B are performed most of the time (eighty percent) in an ambulatory surgery center and not in a hospital setting and it was normal for plastic surgery patients to stay twenty-three hours or longer in an ambulatory surgery center. Dr. Young indicated there is no clear rule on how long the type of cosmetic plastic surgery operations such as were performed on Patient A or Patient B should last.

Although the circumferential lower body lift performed on Patient A would, by itself, necessarily require an overnight stay with monitoring, that overnight stay did not need to be in a hospital. Dr. Young stated that the Respondent did not fail to provide quality medical care to Patient A by planning and performing her procedures as one continuous operation instead of staging the procedures. Dr. Young also testified that, in his opinion, the fluid input and output of Patient A during her operation did not violate the required standard of care.

The surgery performed on Patient B was superficial, and, according to Dr. Young, it is typical to perform a combination of the type of procedures that were performed on Patient B. Dr. Young indicated that the Respondent did not fail to provide quality medical care to Patient B by planning and performing his procedures as one continuous operation.

Dr. Young's opinions were based on his understanding that EI was a free-standing ambulatory surgery center.

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<sup>11</sup> In his testimony, Dr. Young did not further describe the entity that he referred to as "Joint Commission." (Tr. 477) Presumably, Dr. Young was referring to the Joint Commission on the Accreditation of Health Care Organizations.

The Respondent testified in his own behalf and also as an expert witness in plastic surgery and aesthetic plastic surgery, including the assessment of patients for plastic surgery and the management of patient fluids during surgery. His *curriculum vitae* reveals that he has extensive training and experience in plastic and reconstructive surgery. In 1985, the Respondent was board certified by the American Board of Plastic Surgery. The Respondent has been an Instructor and Clinical Assistant Professor in plastic surgery at the Johns Hopkins School of Medicine and at the University of Maryland School of Medicine. He has made numerous presentations on plastic surgery topics to medical peers at workshops, seminars and professional meetings as a visiting professor and invited lecturer. The Respondent lists over two hundred publications, books, video movies or book chapters on his *curriculum vitae*. (R. Ex. 1)

The Respondent described his practice at EI, the facility itself, and the surgeries that he performed on Patient A and Patient B. The Respondent stated that the environment provided for his patients at EI, in terms of medical care and safety, was exactly the same as in a hospital, with the exception that more individual attention was provided at EI. In his testimony, the Respondent stated that the amount of fluids administered to Patient A were appropriate and not excessive. According to the Respondent, it was within the standard of care to plan and conduct Patient A's surgical procedures and Patient B's surgical procedures at EI as they were performed.

The expert witnesses differ in their opinions. Faced with two diametrically opposed opinions of what constitutes the "standards . . . for the delivery of quality medical and surgical care," one opinion having been expressed by Dr. Brown and the opposing opinions having been expressed by Dr. Young and the Respondent, I must determine whether the State has met its burden to prove by a preponderance of the evidence that the Respondent violated section 14-404(a)(22).

## ESTHETIQUE INTERNATIONALE

To begin, it is necessary to consider whether EI should be considered to be a free-standing ambulatory surgery facility or an office-based surgery facility. A quotation from an article entitled "Patient Safety in Office-Based Surgery Facilities: 1. Procedures in the Office-Based Surgery Setting" published by the American Society of Plastic Surgeons brings the question into clearer focus:

Our current health-care delivery system has become increasingly complex, making it possible to deliver health care which is technically superior to that previously offered. This is particularly true with regard to surgical services that are delivered in the outpatient setting. In fact, **most surgical procedures are performed in one of three outpatient settings: hospital-based, free-standing ambulatory surgery centers, or office-based surgery facilities.** The office setting, in particular, has many advantages for the plastic surgeon and his or her patients. These advantages include greater control over the schedule, greater privacy for the patient, convenience, and increased efficiency and consistency in nursing staff and support personnel.

(Bd. Ex. 26, page 1338, emphasis added)

Numerous medical articles were submitted by the parties into the record. Neither party brought attention to any definition for an ambulatory surgery center as distinguished from an office-based surgery facility in those articles. However, in his testimony, Dr. Young provided a description of the differences between an ambulatory surgery center and an office-based surgery facility:

Q. What is the difference between an ambulatory surgery center and an office-based outpatient surgery?

A. I'm sorry, and office-based?

Q. Yes, sir.

A. Well, office-based facilities usually have less resources. They're usually smaller. There's less control over things. And there's not a real certification process for it.

Whereas in contrast for ambulatory surgery centers the requirement by the Society is that they be certified by a [certifying] organization. And the

primary one that does that is called Quad A.

And almost—the vast, vast majority of the surgery centers where board certified plastic surgeons operate are certified by Quad A. They have very strict requirements that relate to safety in the operation of those facilities to try to ensure patient safety.

And you have to be board certified. And you have to operate by other rules. You have to either have privileges at a hospital or an agreement with someone who has privileges for admission in case that becomes necessary for some reason. And those are some of the main criteria.

\* \* \*

Q. So when you use -- in your report, when are you use the term ambulatory surgical facility -- let's get this clear -- what are you describing?

A. A facility that is certified by some organization, such as Quad A or the state that gives you permission to perform surgery at that facility and manage the postoperative care for at least 24 hours.

Q. And do you also recognize that, just as in Missouri, the state might have regulations?

A. Yes.

Q. And is it your understanding that with a Quad SF-4 facility there is a certification that this facility director has to certify that this facility meets state regulations?

A. Yes.

Q. And that the state regulations supersede the Quad SF-4 criteria if they're more stringent?

A. I don't know if they're more stringent. I would assume state law would exceed some organizational law.

(Tr. 415-416, 478-479)

Considering the three possibilities outlined in the article quoted above, EI, clearly, was not a hospital-based outpatient setting. For purposes of the standard of care analysis, there are two other possibilities. Although he had never been at EI, Dr. Young indicated in his testimony that EI was a free-standing ambulatory surgery center and not an office-based surgery facility:

Q. What is your understanding of the facility that [Respondent] had at Esthetique Internationale, which we've been calling EI?

A. It was a Quad A certified ambulatory surgery facility.

Q. And would you characterize it as an office-based facility or an ambulatory surgery center?

A. No. It was clearly an ambulatory surgery center. And part of that Quad A certification is that they audit the facility so they have an idea of what the quality of care is that goes on there.

So it's an ongoing process. It's not just you do it once, you get the license, and then you're free to do whatever you want. There's quality control methods.

(Tr. 416-417)

In keeping with Dr. Young's opinion, for EI to meet the criteria for a free-standing ambulatory surgery center and not an office-based surgery facility, it must be licensed by the State of Maryland or have AAAASF ("Quad-A" or "SF-4") certification that entitles it to perform the surgery done at that facility and to manage the postoperative care of a patient for at least 24 hours.

EI was never licensed by the State as an ambulatory surgical facility/center. Regardless, the Respondent suggests that EI was a free-standing ambulatory surgery facility/center, was recognizes as such by an agency of the State of Maryland, and did not need to be licensed in order to provide services to its patients. To prove this point, the Respondent relies upon a September 28, 1999 letter from the Maryland Health Resources Planning Commission<sup>12</sup> to one of the Respondent's employees. The letter states, in pertinent part:

This is in response to your letter of August 18, 1999 concerning the relocation of an existing single operating room freestanding ambulatory surgery facility operated by your client, [Respondent] . . . On February 18, 1999, [Respondent] received a Determination of Non-Coverage from Certificate of Need for the facility named Plastic & Aesthetic Surgical Center of Maryland . . . the Commission will amend our files to show that your client's [freestanding ambulatory surgery facility] will change its name to Esthetique International Surgical Center . . . You have provided on behalf of [Respondent] a copy of the line diagram for the newly relocated [freestanding ambulatory surgery facility], and provided a signed statement affirming that the room designated as the operating room will be the only room in

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<sup>12</sup> The Commission, an independent body established within the Department of Health & Mental Hygiene in 1993, is the predecessor of the Maryland Health Care Commission created in 1999.

which surgical procedures will be performed. The remaining facts from your previous determination request remain the same.

(R. Ex. 17)

In order to fully address Respondent's argument, it is necessary to examine the statutory provisions, as they existed in 1999, relative to the requirement to obtain a certificate of need, which is what the above letter addresses. It is also important to note that the certificate of need is wholly distinct from the license requirement for a freestanding ambulatory surgery facility. The above letter did not absolve EI of the license requirement, and his attempt to conflate the two requirements must necessarily fail. Thus, I must examine whether EI was required to obtain a license from the State.

At the time of the September 28, 1999 letter from the Commission, "ambulatory surgical facility" and "certificate of need" were defined by statute as follows:

(b)(1) "Ambulatory surgical facility" means any center, service, office, facility, or office of one or more health care practitioners or a group practice, as defined in § 1-301 of the Health Occupations Article, that:

- (i) Has two or more operating rooms;
- (ii) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and
- (iii) Seeks reimbursement from payors as an ambulatory surgical facility.

. . . . .

(c) "Certificate of need" means a certification of public need issued by the Commission under this Part II of this subtitle for a health care project.

Md. Code Ann., Health-Gen. § 19-101(b), (c) (1996 & Supp. 1998).<sup>13</sup>

The law further required that a certificate of need be obtained before an ambulatory care facility, as defined above, could provide services in this State:

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<sup>13</sup> Renumbered as Health-General § 19-114 and amended by Acts 1999, ch. 702, §§ 2, 5, eff. Oct. 1, 1999.

A certificate of need is required before an ambulatory care facility:

(1) Offers any health service:

- (i) Through a health care facility;
- (ii) In space leased from a health care facility; or
- (iii) In space on land leased from a health care facility . . . .

Md. Code Ann., Health-Gen. § 19-117(1) (1996).<sup>14</sup>

On August, 18, 1999, one of the Respondent's employees sent a letter to the Executive Director of the Commission that detailed a change in name and location for the Respondent's facility, now to be known as EI. The letter stated that the surgical suite at EI had one operating room. The letter also stated in regards to the billing process: "[t]he office does not receive a technical or facility fee, and the operating room is used exclusively by [Respondent] for his patients." (Bd. Ex. 29, page 7/14) The letter contains an addendum from the Respondent, wherein he stated:

In the proposed ambulatory surgical facility, no more than one room will be used as an operating room in which surgical procedures are performed. I hereby declare and affirm under the penalties of perjury that the information I have given in this determination request for non-coverage under certificate of need is true and correct to the best of my knowledge and belief.

(Bd. Ex. 29, page 8/14) This letter apparently provided enough information to allow the Commission to exempt the Respondent from the requirements in section 19-117 because it determined that his facility was not an ambulatory surgical facility as defined by section 19-101. I see no reason to doubt the correctness of the advice that the Commission gave to the Respondent.

At the relevant times, Subtitle 3B of Title 19 regulated freestanding ambulatory care

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<sup>14</sup> Renumbered as Health-General § 19-126 and amended by Acts 1999, ch. 702, § 2, eff. Oct. 1, 1999.



facilities, included a definition of an ambulatory surgical facility, and established a licensing requirement. The definition follows:

(b) *Ambulatory surgical facility*. – (1) “Ambulatory surgical facility” means any center, service, office facility, or other entity that:

(i) Operates primarily for the purpose of providing surgical services to patients requiring a period of postoperative observation but not requiring overnight hospitalization; and

(ii) Seeks reimbursement from payors as an ambulatory surgery center.

(2) “Ambulatory surgical facility” does not include:

. . . .

(iv) The office of a group of health care practitioners with not more than one operating room if:

1. The office does not receive a technical or facility fee; and
2. The operating room is used exclusively by members of the group practice for patients of the group practice . . . .

Md. Code Ann., Health-Gen. § 19-3B-01(b) (2005).<sup>15</sup> A license was, and is, required for a facility that meets the definition of an ambulatory surgical facility found in section 19-3B-01(b):

(a) *License required*. – A freestanding ambulatory care facility may not operate in the State unless the Secretary has granted the facility a license.

(b) *When issued*. – The Secretary shall issue a license to an applicant that meets the requirements of this subtitle and all applicable regulations adopted by the Secretary.

Md. Code Ann., Health-Gen. § 19-3B-02(a), (b) (2005).<sup>16</sup>

EI does not fit the definition of an ambulatory surgical facility that is outlined in section

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<sup>15</sup> The same statute as appears in the 2005 Replacement Volume was the law in Maryland at all times relevant with the exception that former subsection (c) was redesignated as section (b). Md. Code Ann., Health-Gen. § 19-3B-01(b) (2000).

<sup>16</sup> The same statute as appears in the 2005 Replacement Volume was the law in Maryland at all times relevant. Md. Code Ann., Health-Gen. § 19-3B-02 (2000).

19-3B-01(b). First, the Respondent's practice at EI consisted "entirely [of] cosmetic self-pay patients." (Bd. Ex. 29, page 3/14) In other words, all payments were made directly by the patient and, at all times relevant, the Respondent did not "[seek] reimbursement from payors." Md. Code Ann., Health-Gen. § 19-3B-01(b)(1)(ii). Second, the office did not receive a technical or facility fee. Finally, the operating room was used exclusively by the Respondent for his patients.

The Respondent is correct in his assertion that he was not required to be licensed under Subtitle 3B. However, as illustrated by the cited statutes, the September 28, 1999 letter is only useful as evidence to confirm that EI was not subject to those statutory requirements. The Commission's letter does not demonstrate that EI was an ambulatory surgical facility/center for the standard of care analysis in this case.

Although the Respondent was not required to be in compliance with the cited statutory provisions requiring the licensing of freestanding ambulatory surgery facilities, this does not end our inquiry. I am still left to sift through the evidence in the record to determine if EI should have the status of an ambulatory surgery facility/center in the matter *sub judice*.

During September 2004, the Respondent performed surgery on Patient A. During February 2005, the Respondent performed surgery on Patient B. During 2004 and 2005, EI held an AAAASF certification that it met all of the standards of a Class C ambulatory surgery facility. The Respondent submitted a copy of the AAAASF Standards and Checklist for Accreditation of Ambulatory Surgery Facilities admitted into the record as R. Ex. 7. The definitions of facility classes found in that document reflect that different types of anesthesia or sedation may be administered to patients for the surgical procedures that may be performed dependent on the

approved class of the ambulatory surgery facility.

The standards document contains the following rules for a Class B or Class C ambulatory surgery facility on extended stays:

If overnight stays are permitted, the facility is in compliance with all pertinent local and state laws and regulations.

If 23 hour stays are permitted, the facility is in compliance with all pertinent local and state laws and regulations.

(R. Ex. 7, page 13) The applicable AAAASF standards on extended stays seems consistent with the notion that a Class C ambulatory surgical facility may perform surgery at that facility and manage the postoperative care on a patient for at least twenty-three (or twenty-four) hours, but only if that is in compliance with state laws and regulations. As the Maryland definition of an ambulatory surgical facility does not include a facility that allows for overnight care, scheduling Patient A and Patient B for stays at EI for twenty-three hours seems to be inconsistent with the AAAASF standards quoted above.

Intuitively, the significance of an AAAASF certification is that it demonstrates that the facility to which it is issued meets the AAAASF standards for an ambulatory surgery facility. One of the standards for AAAASF certification of a facility as a Class A, Class B, or Class C ambulatory surgery facility is that “there is a written transfer agreement with a local accredited or licensed acute care hospital which is approved by the [hospital’s] medical staff or the surgeon has privileges to admit patients to such a hospital after having surgery in the facility.” (R. Ex. 7, page 16, emphasis in original) The Respondent had no privileges to admit patients at any Maryland hospital since 2003. At no time did a written transfer agreement exist between EI and any local acute care hospital.

The fact that Respondent had no admission privileges at a hospital and there existed no written transfer agreement appears to be at odds with the fact that EI held an AAAASF certification that it met all of the standards of a Class C ambulatory surgery facility for calendar years 2004 and 2005. However, when the facts of the AAAASF inspection, review and certification process are considered, the confusion vanishes. AAAASF did not conduct an annual on-site inspection and review of EI. Between 1999 and 2005, AAAASF conducted two on-site inspections. The initial on-site inspection and certification process of EI took place on December 20, 1999. An on-site re-inspection took place on December 19, 2002. Interim year evaluations between and following the on-site inspection years were, apparently, limited to a review of a self-evaluation submitted by EI. For 2004 and 2005, the Class C ambulatory surgery facility certification issued to EI was based on self-evaluations submitted to AAAASF by the Respondent, the EI facility director.

Since the facts as found do not meet the relevant AAAASF standard, it is reasonable and permissible to infer that AAAASF was not made aware in the Respondent's self-evaluation submissions that (since 2003) he had no hospital admission privileges and that EI had no written transfer agreement with any acute care hospital.

In his testimony, quoted above, of the difference between an ambulatory surgery center and an office-based surgery facility, Dr. Young indicated that the surgeon needed to have hospital privileges or "an agreement with someone who has privileges for admission in case that becomes necessary for some reason." Dr. Young's testimony is not the AAAASF standard. According to AAAASF, in the absence of admitting privileges, a written transfer agreement approved by the medical staff of the receiving hospital is required. Dr. Young does not know or

does not agree with the AAAASF standard on this point. In the absence of an explanation, insofar as Dr. Young's opinion differs from the standards of a generally recognized certifying organization, it cannot be given any weight and is rejected. It was also noted that Dr. Young's knowledge of AAAASF certification appears to be incomplete. For example, AAAASF has four possible classes or levels of certification of a facility as an ambulatory surgery facility. In answering a question, Dr. Young did not seem to realize this. (Tr. 416: 15-17)

Dr. Young considers EI to have been an ambulatory surgery center because it held an AAAASF certification. The fact that EI did not meet all of the AAAASF standards for certification as a Class A/B/C ambulatory surgery facility during 2004 and 2005 undercuts Dr. Young's opinion (and the Respondent's claim) that it should be afforded that status for the purposes of the standard of care analysis. In his testimony, quoted above, Dr. Young indicated that one of the "main criteria" is admission privileges at a hospital or a substitute for admission privileges. The only substitute for admission privileges recognized by the AAAASF is a written transfer agreement approved by the medical staff of the local acute care hospital. The purpose of the quoted AAAASF standard must be to allow for a seamless transfer of a patient to an acute care hospital at the direction of the physician practicing in the ambulatory surgery facility.

Regardless of the AAAASF issued certification for 2004 and 2005 and Dr. Young's opinion, the Respondent's claim that EI should be considered to be a free-standing ambulatory surgery facility/center for the purposes of the standard of care analysis in this case is rejected. EI did not meet all of the AAAASF standards during 2004 and 2005. EI is not entitled to be considered as a free-standing ambulatory surgery facility/center because the facts as found are inconsistent with all of the AAAASF standards for a Class A/B/C ambulatory surgery facility.

In his testimony, Dr Brown indicated agreement with the notion advanced by Dr. Young and the Respondent that a free-standing ambulatory surgery center provides a greater safety net than does an office-based surgery facility. According to Dr. Brown, other physicians practice at such a facility and, typically, it is a multi-specialty practice, although separate from a hospital. The statutory definition of a free-standing ambulatory surgery facility found in Subtitle 3B of Title 19 appears to be consistent with Dr. Brown's views. For Dr. Brown, an ambulatory surgery center functions more like a hospital and less like a physician's office:

JUDGE: I'm having a little trouble understanding the difference between an office-based surgical center and an ambulatory surgery center. Am I correct in understanding what you told me that there is a supervisory staff – some director or someone who makes decisions at the ambulatory surgical center – ambulatory surgi-center that would be separate and independent from the employed physician?

THE WITNESS: Yes.

JUDGE: Is that the distinction?

THE WITNESS: That's a distinguishing feature, yes.

(Tr. 209)

Dr. Brown suggests that an ambulatory surgery center is distinguished by the availability of independent control or influence from someone other than the practicing surgeon. In his description of an office-based surgery facility, Dr. Young mentions "less resources," "smaller," and "less control over things." EI had only one operating room and no one other than the Respondent, the practicing surgeon, in control over events. Even Dr. Young mentioned that size, resources, and control are part of the difference between an ambulatory surgery center and an office-based surgery facility. During cross examination, Dr. Young mentioned there are different facility models known as ambulatory surgery facilities. Dr. Young currently practices in an ambulatory surgery center that has four operating rooms, adjacent to, and affiliated with an

acute care hospital. The facility in which Dr. Young currently performs surgery is the type of facility that Dr. Brown would, I believe, properly recognize as a free-standing ambulatory surgery center within the meaning of medical literature upon which he based his opinion in this case. The facility in which Dr. Young currently performs surgery is the type of facility that appears to match the Maryland definition of an “ambulatory surgical facility.” Md. Code Ann., Health-Gen. § 19-3B-01(b). EI was a different type of facility; for the purposes of the standard of care analysis and Maryland law, it was, at all times relevant, an office-based surgery facility.

#### PERFORMING MULTIPLE PROCEDURES ON PATIENT A AND PATIENT B AT EI

It is clear that the Respondent performed multiple plastic surgery procedures on Patient A during one continuous operation. On February 23, 2005, the Respondent performed four procedures on Patient A: a bilateral thigh circumferential suction assisted lipectomy, abdominoplasty, a circumferential lower body lift, and also a ventral hernia repair (with mesh). The surgical portion of Patient A’s procedures took approximately nine hours and thirty-seven minutes; total anesthesia time was approximately ten hours and twenty-seven minutes. In his Operative Report on Patient A, in a section entitled “Disclaimer of Multiple Procedures,” the Respondent wrote:

The patient requested **multiple procedures** and she understood very well that this will take many hours. Since we were not anticipating blood loss from those surgeries, we decided to proceed with this **with the understanding that the complication rate might be slightly increased**. The patient has been made aware in the event that some complication arises (*sic*) during or immediately after surgery, she might need to be transferred to the hospital.

(Bd. Ex. 5, OR10693, emphasis added)

It is equally clear that the Respondent performed multiple plastic surgery procedures on Patient B during one continuous operation. On September 30, 2004, the Respondent performed

five procedures on Patient B: an endotemporal midface lift with Bichat's fat pad excision bilateral, a cervicofacial lift, bilateral cheek implants, a chin implant, and also hair transplantation to bilateral temporal and moustache areas. The surgical portion of Patient B's procedures took approximately twelve hours and seven minutes; total anesthesia time was approximately twelve hours and forty minutes. Because of the length of time it was taking, the Respondent changed his plan for the operation and did not perform a lower lid skin excision blepharoplasty (removal of excess skin from lower eyelids) on Patient B. In his Operative Report on Patient B, in a section entitled "Disclaimer of Multiple Procedures," the Respondent wrote:

The patient requested **multiple procedures** and he understood very well that this will take many hours. Since we were not anticipating significant blood loss from those surgeries, we decided to proceed with this **with the understanding that the complication rate might be slightly increased**. The patient has been made aware in the event of some complication arises (*sic*) during or immediately after surgery, he might need to be transferred to the hospital.

(Bd. Ex. 14, OR11012, emphasis added)

EI was an office-based surgery facility. This was the perspective Dr. Brown had when he conducted his peer review and considered if the Respondent had violated the standard of care when he performed surgery on Patient A. According to Dr. Brown, the Respondent violated the standard of care by conducting Patient A's multiple plastic surgery procedures as a continuous operation lasting over nine and a half hours:

Q. Sure. I was wondering if you had an opinion about whether the Respondent's combination of the bilateral thigh liposuction plus the circumferential body lift, which included a tummy tuck, met the standard of quality care.

A. Again, I feel that the combination – the overall combination of procedures and the duration of the procedure did not meet the standard of quality care. The absolute combination of thigh liposuction and a lower body



lift does not necessarily not meet the standard of care because these things might be minute in one patient or more involved in another patient.

So, it's really not the absolute procedures that are performed in combination, but it's the duration of those procedures. So my opinion is based on that.

However, on the average given patients that receive lower body lifts and other procedures, combining a lower body lift or circumferential abdominoplasty with other procedures is often not performed without being in a setting where you know the patient is in an area -- in a hospital setting that's going to stay for some time.

\* \* \*

Q. Thank you. In the Respondent's expert's -- Dr. Young's report -- he states that, "It was appropriate in this instance" -- in Patient A's case -- "to perform the liposuction in conjunction with the medial thigh lift and the body lift." Do you agree?

A. I understand the concept from the standpoint as to best aesthetic outcome. However, I still take issue with the overall combination of procedures. I feel that, you know, if you look at the operative report you could stop at 10695, and that duration would probably fall within what we're considering to be the standard of care. Does that make sense?

JUDGE: I didn't quite follow what you said.

THE WITNESS: What I'm saying is I think that liposuction of the circumferential thighs as performed -- perhaps even the anterior abdominoplasty. But the lower body lift and the thigh lift adds an undue level of duration and risk in this situation.

(Tr. 94-95, 97-98)

During his peer review, Dr. Brown also had to consider if the Respondent had violated the standard of care when he performed surgery on Patient B. According to Dr. Brown, the Respondent violated the standard of care by conducting Patient B's multiple plastic surgery procedures as a continuous operation lasting over twelve hours:

Q. Do you have an opinion as to the number of procedures that were performed at one time?

A. Well, it lists it here that there were at least five procedures performed.

Q. Right. And do you have an opinion as to whether that met -- well, is there a standard of care with regard to the procedures performed.

A. I don't have an opinion on that actually because I don't think that

– I think that the absolute number of procedures doesn't dictate what's the standard of care. It's what procedures are performed and how long it takes you as an individual to perform those procedures and the combination of those procedures. So, again, I take question as I did with Patient A as far as the duration and combination of all these procedures.

Again, it's like a puzzle. You can pick and choose which ones you feel are going to be combined appropriately for the patient's, you know, best outcome in a timely fashion so that the duration does not exceed what would be acceptable from a safety standpoint.

\* \* \*

Q. Do you have an opinion with regard to the duration of the procedures that the Respondent performed?

A. I do. I felt that the duration of the procedures falls outside what would be considered the standard of care in an outpatient surgical setting.

Q. And on what do you base your opinion?

A. Again, based on practice, training and the review of the literature.

(Tr. 116-117, 118)

In his testimony, Dr. Brown indicated that the standard of care was breached because of the type and number of procedures performed on Patient A and Patient B along with the decision to combine those procedures as one continuous operation resulting in the lengthy duration of the operations. Dr. Brown maintains that the procedures could have been and should have been staged, and the failure to do so increased the risk of complications. The Respondent's operative reports on Patient A and Patient B, quoted above, reflect that the complication rate might be increased, albeit "slightly." Dr. Young and the Respondent both maintain that the Respondent did not fail to provide quality care to Patient A and Patient B by planning and performing their multiple procedures as continuous operations at EI. However, the Respondent's assertion that the environment provided for his patients at EI, in terms of medical care and safety, was exactly the same as in a hospital is rejected. A hospital setting provides a greater array of support than an office-based surgery facility in that other equipment and medical staff are available in the

hospital setting to assist with patient care and safety. During closing argument, the Board's representative brought attention to an excerpt from the deposition of Amy Swank, the Respondent's CRNA. That excerpt illustrates the type of differences:

Q. Is there any difference between the recovery room at [Respondent's] outpatient surgery center and a fully staffed PACU?

A. Yes.

Q. What's the difference?

A. There is more staff and it has more access to other personnel in case of an emergency. And also usually a fully staffed PACU the staff have – are certified in being PACU nurses.

(R. Ex. 6, pages 161-162) In his testimony, the Respondent acknowledged that if a true emergency arose, he would transfer a patient to the nearest hospital. (Tr. 358-359) Although an ambulatory surgery facility provides a greater safety net than does an office-based surgery facility and may approximate the medical care and safety of an acute care hospital, I have determined that EI is an office-based surgery facility and not an ambulatory surgery facility. Dr. Young and the Respondent's opinions are based on a faulty assumption, that EI should be considered to be an ambulatory surgery facility/center. As his opinions are aligned with the true picture of EI as an office-based surgery facility, Dr. Brown's opinions, quoted above, on the required standard of care in the Respondent's treatment of Patient A and Patient B are more persuasive and accepted and the opposing opinions are rejected.

Further, the medical literature indicates that one consideration on where plastic surgery procedures should be performed is the anticipated blood loss. "If the anticipated blood loss is more than 500 cc for an average patient, the procedures should be performed only where adequate blood components are **immediately available**." Horton, J.B., *et al.*, Patient Safety in the Office-Based Setting, *Plastic and Reconstructive Surgery*, 66e, 2006. (Bd. Ex. 23, emphasis added) The

Respondent had a contract with the American Red Cross to have blood products, if needed, delivered to EI. After a request for blood products, EI could expect to receive a delivery in about an hour and a half.

In his testimony, the Respondent stated that he had expected Patient A's blood loss to be less than 500 cc. The Respondent explained that he had planned to use tumescent fluid during the liposuction to reduce Patient A's surgical blood loss. According to Dr. Young's testimony, Patient A's blood loss should have been expected to be around 500 cc give or take a couple of hundred cc on either side of 500. However, in response to questions about the anticipated blood loss from each procedure performed on Patient A, Dr. Young indicated that the blood loss anticipated on an average patient would be:

- a. 200 – 240 cc from a bilateral thigh circumferential suction assisted lipectomy
- b. 200 – 300 cc from abdominoplasty
- c. 400 – 500 cc from a circumferential lower body lift

No reasoned explanation was offered why the anticipated blood loss from a surgical combination of these procedures should add up to less than the sum of the loss from each procedure. Dr. Brown pointed out that Patient A's blood loss during the procedures performed on her was 800 cc and he indicated that the combination of procedures performed on her should not have been performed where adequate blood products were not immediately available. This actual 800 cc blood loss matches the lower end of the sum of the expected loss from each of the three procedures, quoted above.

Considering all of the evidence in this record, Dr. Brown's opinion seems more credible and is more persuasive than Dr. Young's opinion and the Respondent's claim. For pre-operative

planning, Patient A's expected blood loss should have been significantly more than 500 cc and the standard of care would require that adequate blood components be immediately available. Upon cross-examination, Dr. Young indicated that he did not know if EI had blood products immediately available. Later in his testimony, Dr. Young suggested that an hour and a half timeline for the delivery of blood products would meet the criteria of being immediately available because of the superficial nature of the procedures being performed. This logic seems a bit thin. The blood loss guideline, quoted above, is proposed for plastic and reconstructive surgery. I daresay most plastic surgical procedures could properly be described as superficial from a general surgical perspective. The notion that "immediately available" means an hour and half delay is rejected as at odds with the plain meaning of words and common sense. For the purpose of the required standard of care, the procedures the Respondent performed on Patient A should not have been performed at EI as blood products were not immediately available.

#### PATIENT A - FLUID MANAGEMENT

In his testimony, Dr. Brown indicated that the Respondent failed to manage Patient A's fluids (input and output) appropriately during her intraoperative period and the post-operative period. "[M]y opinion was that she received more fluid than was probably necessary." (Tr. 109: 3-4) Dr. Brown points out that Patient A was putting out about four times the expected amount of urine (50 cc per hour) during the intraoperative period. In his peer review report, Dr. Brown did not discuss insensible loss as a factor in Patient A's fluid management and he considers the impact of insensible loss on Patient A's fluid management to have been negligible. During the post-operative period, Patient A was receiving 200 cc of IV fluid per hour. Dr. Brown believes that this amount of IV fluid was

more than was necessary as Patient A was not a trauma case and her surgery had not involved internal cavities.

The Respondent stated that the amount of fluids administered to Patient A were appropriate and not excessive. The Respondent points out he had ordered that Patient A receive 150 cc of IV fluid per hour during the post-operative period and he surmises that his order may have been changed by Dr. Zacharek or not followed by the PACU nurse. Dr. Young stated that the Respondent's order for 150 cc of IV fluid during the post-operative period "would be perfectly reasonable." (Tr. 512: 22) Dr. Young testified that he would have ordered that Patient A receive 125 cc of IV fluid per hour during the post-operative period, but it is a matter of judgment and, as there were no clinical signs of excessive fluids, there was no breach of the required standard of care.

In his expert report, Dr. Young explains why the fluids input and output of Patient A during her operation did not violate the required standard of care. According to the Respondent's records, Patient A's height and weight before her surgery was variously reported to be five feet, four inches and 118 pounds or five feet, three inches and 120 pounds. The OCME conducted a post-mortem examination of Patient A. Her weight was reported by that office at autopsy to be 152 pounds. The State relies heavily on this weight gain in support of its argument on fluid management. In his report, Dr. Young discusses Patient A's inputs/outputs (I/O), insensible fluid loss, tissue loss, and this weight gain evidence:

The patient's postmortem weight gain of 34 pounds (118 preoperatively to 152 pounds postmortem) is unclear. Her I/O's including the tissue removed (but not including insensible losses) is 4,610 cc, which is equivalent to 10.1 pounds, if insensible losses are taken into consideration then I/O's are 1233cc (2.7 pounds).

It's unknown what the patient ate or drank while she was at home, but it's unlikely that she ingested [34] pounds of food and liquid. The drains, pain pump, and foley catheter (with urine) add to the post mortem weight. The most likely explanation is that her preoperative is not correct, as patients frequently under report their weight.

(R. Ex. 3, page 13)

During and after the surgery, Patient A received 9,600 cc of IV fluid. Her outputs during the intraoperative period and post-operative period were 6,420 cc. Each liter of IV fluid has a weight of approximately 2.7 lbs. Ignoring insensible loss and tissue loss for the moment, even if Patient A had received 3,200 cc of excess IV fluid, the weight gain from the excess 3.2 liters would only be a weight gain of 9-10 lbs and not 34 lbs.

Dr. Brown's opinion regarding the excess fluids given to Patient A did not take insensible loss into consideration. The detailed explanation and logic in Dr. Young's report seems sound. There is a strong probability that Patient A underreported her weight; if she did not, why would a woman five feet, four inches tall and weighing 118 lbs desire to have the plastic surgery procedures performed on her that Patient A underwent? Each expert indicated that there are recognizable clinical signs of when a patient is given excessive fluids. Yet, all of the experts agreed that Patient A did not display any of the clinical signs of excess fluids. The burden of proof in this case is by a preponderance of the evidence and rests with the State. The State has failed to prove, by a preponderance of the evidence that the Respondent mismanaged Patient A's fluids.

#### SANCTION

Disciplinary proceedings against a physician are not intended to punish the offender but rather to protect the public. *McDonnell v. Comm'n on Medical Discipline*, 301 Md. 426, 436 (1984). The Court of Special Appeals has held that an administrative agency with disciplinary

and licensing authority “has broad latitude in fashioning sanctions within [those] legislatively designated limits.” *Cornfeld v. State Bd. of Physicians*, 174 Md. App. 456, 486 (2007) (citing *Neutron Prods., Inc. v. Dep’t of Environment*, 166 Md. App. 549, 584, *cert. denied*, 392 Md. 726 (2006) and *Blaker v. State Bd. of Chiropractic Examiners*, 123 Md. App. 243, 264-65, *cert. denied*, 351 Md. 662 (1998)).

Although section 14-404 of the Health Occupations Article and COMAR 10.32.02.02B(30) each list possible sanctions, neither section 14-404 nor any regulation provides guidance for assessing sanctions. Even so, I am mindful that, as with most licensing statutes, the Medical Practice Act allows the imposition of sanctions not as a way of meting out punishment to wayward physicians, but as a means of remediating improper conduct and protecting the public. Taking a cue from other licensing statutes,<sup>17</sup> I will use the following criteria as a guide to determine the proper sanction to recommend for the Respondent’s violations:

- What is the Respondent’s history of violations?
- How serious were those violations?
- What was the harm caused by those violations?
- Was the Respondent acting in good faith?

The Respondent is subject to sanction for violations of the standard of care. The Respondent has been licensed in Maryland for approximately thirty years and has had no prior violations. Thus, the first factor seems to mitigate the argument for a harsh sanction.

The severity of the violation must also be taken into consideration when determining the

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<sup>17</sup> See, e.g., section 17-322(c)(2) of the Business Occupations and Professions Article (2010) which governs real estate brokers and agents.



proper sanction. I have found that the Respondent violated the standard of care by performing multiple plastic surgery procedures as a continuous operation on two patients in an office-based surgery facility rather than a freestanding ambulatory surgical center or a hospital. The record reflects that after a series of tragic and unnecessary deaths in the 1990s, the American Society of Plastic Surgeons took efforts to study and improve patient safety in plastic surgery procedures. Guidelines covering the recommended length and the settings of where operations should be held were discussed and published. The guidelines were not absolutes, but they are key factors in promoting patient safety and determining the requisite standard of care. There is a suggestion in the record that patient preference and convenience should be important in determining the surgical setting for plastic surgery and in the decision to stage or combine plastic surgery procedures. A physician must provide treatment consistent with the standard of care and a patient's preference and convenience plays no part in determining if the standard was met. The longer and more extensive an operations becomes, the higher the risk of complications. Even the Respondent, in his operative reports on Patient A and Patient B, recognized this increased risk. The operations the Respondent performed on Patient A and Patient B were extremely lengthy and the planned post-operative period called for extended overnight stays. These surgeries, as planned, should have been performed, if at all, in a free-standing ambulatory surgery center or a hospital.

The severity of the Respondent's violations is further illustrated by referencing the AAAASF standards regarding extended stays and Maryland statutes, cited herein. Both patients were scheduled for 23-hour stays, and Patient A was kept overnight after her surgery. Under AAAASF standards, a Class C ambulatory surgical facility may perform surgery at that facility and manage the postoperative care on a patient for 23 hours or overnight, but only if that if state laws

and regulations permit that particular facility to do so. The Maryland definition of an ambulatory surgical facility does not include overnight postoperative care. Thus, even setting aside the fact that Respondent's AAAASF certification was maintained through deception (as I will address below), he did not comply with the AAAASF standards governing 23 hour and overnight stays. Nor has he complied with the Maryland requirements for ambulatory surgical facilities. The Maryland statute exists to protect patients by providing a minimum standard with which surgical providers must comply. By performing extensive and lengthy surgeries in an office-based surgical facility, and then keeping one of the patients for post-operative care overnight, the Respondent placed his patients at a very serious and unnecessary risk to their safety.<sup>18</sup> There should be zero tolerance for a physician who takes unnecessary risks with patient safety; this is especially true where a physician performs surgery involving general anesthesia on "healthy" individuals.

The State did not prove that the Respondent's violations of the standard of care caused the death of Patient A or Patient B. The State's representative argues that the question of outcome, as distinguished from causation, has unique relevance to the sanctions inquiry in this case. The outcomes were the most serious of all outcomes, namely, the death of two of the Respondent's patients after surgeries that lasted nine hours and thirty-seven minutes (Patient A), and twelve hours and seven minutes (Patient B). I do not agree that outcome, as opposed to causation, should have relevance in determining the appropriate sanction. I am advised that the Board has considered the outcome of a patient's care without the requirement to show that the breach of the standard of care caused the outcome; yet, such a policy should be reduced to written form as a regulation for it to be "settled, preexisting policy," as this type of criteria is not typically found in licensing statutes as a

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<sup>18</sup> The Respondent also planned, apparently, to keep Patient B overnight, but Patient B went into cardiac arrest about one hour and forty minutes after the conclusion of the surgery.

factor to be used in determining a sanction. Md. Code Ann., State Gov't § 10-214 (2009); *See generally Massey v. Secretary, Dept. of Public Safety*, 389 Md. 496 (2005). As no causation of harm had been established by the Respondent's violations of the standard of care, this is a neutral factor in determining a proper sanction.

Whether the Respondent acted in good faith should also be considered. Although the Respondent settled with the estate of Patient A, he did so only under the threat of a civil action. In argument for a sanction, the State's representative implied that the Respondent lacked good faith by filing for bankruptcy following his settlement. However, I will not consider this fact in making a recommendation because it is sufficiently detached from the actual violation of the standard of care.

In a cause of action for defamation, false imprisonment, malicious prosecution and abuse of process against a security guard service, its employee, an attorney, and the attorney's law firm, the Court of Special Appeals observed that:

The definition of good faith, of course, depends on the context, *i.e.*, the particular statute or other rule of law in which it is used. We are bereft of a precise definition of good faith as it is used in § 9, as there is no statutory definition and no cases construing the term.

"Good faith" is a concept frequently encountered in the law; therefore, we turn to the term as it has been defined in similar contexts. Good faith is an intangible quality, with no precise technical meaning. It encompasses, *inter alia*, an honest belief, the absence of any malice or of any design to seek an unconscionable advantage; an individual's good faith is conceptualized within his or her own mind and inner spirit and, therefore, may not be conclusively established by his or her protestations alone. *Doyle v. Gordon*, 158 N.Y.S.2d 248, 259-60 (N.Y.1954). Good faith requires an honest effort to ascertain the facts on which an exercise of power rests, and an honest determination from these facts. *Colket v. St. Louis Union Trust Co.*, 52 F.2d 390, 391 (8th Cir. 1931).

*Laws v. Thompson*, 78 Md. App. 665, 678 (1989).

There are several indications that the Respondent was not acting in good faith with respect to the violations in this case. In 2003, he ceased carrying malpractice insurance, yet he continued to perform surgery. In a deposition, the Respondent explained that he allowed his malpractice insurance to lapse because of the cost of that insurance. (Bd. Ex. 28: pages 11-18) Prospective patients expect a physician to carry malpractice insurance and would be reluctant, indeed, to allow a physician to treat them in any way if they knew the practitioner had no malpractice insurance. (At the very least, a prospective patient would wonder why?) As a result of the absence of malpractice insurance, the Respondent discontinued his admission privileges at any Maryland hospital. The Class C ambulatory surgery facility certification issued to EI for 2004 and 2005 was based on self-evaluations submitted to AAAASF by the Respondent, and I have inferred that AAAASF was not made aware in the Respondent's self-evaluation submissions that (since 2003) he had no hospital admission privileges and that EI had no written transfer agreement with any acute care hospital. This lack of candor in the self-reporting process is hardly surprising considering the fact that the Respondent had continued to perform surgery without malpractice insurance. If the Respondent's judgment would allow him to continue to perform surgery without malpractice insurance, how little a stretch it would be to not disclose a change in information on a form in order to continue to hold onto a certificate that labels EI as an ambulatory surgery facility and to continue his practice. I am left to conclude that the Respondent's failure to disclose on the self-evaluations was intended to gain an "unconscionable advantage" by obtaining the benefits of AAAASF certification without the costs associated with obtaining that certification. I believe that the Respondent's violations of the standard of care were not errors in "good faith." This further suggests that in the Respondent's practice, business decisions are paramount and may

override the best interests of patient safety.

The Board has statutory authority to “suspend or revoke a license” for a single violation of the Medical Practice Act. Md. Code Ann., Health Occ. § 14-404(a)(22) (Supp. 2010). The State’s representative suggested that I should recommend that the sanction of revocation be imposed upon the Respondent’s privilege to practice medicine. The absence of prior violations of the Medical Practice Act is a factor in the Respondent’s favor. I have discounted the argument that outcome as opposed to causation of harm should be considered in recommending a sanction; as I have mentioned, that factor neither supports nor discourages a harsh sanction. Yet, I cannot forget that the Respondent violated the standard of care in performing surgery on two of his patients and, I believe, in a manner that took unnecessary risks with their safety. Protection of the public must be our overriding concern. Taking all of the above-noted criteria into account, because of the severity of the violations and the Respondent’s lack of good faith with regard to those violations, I am persuaded there are sufficient grounds to propose a revocation of the Respondent’s license to practice medicine and therefore that is the appropriate sanction.

### **CONCLUSIONS OF LAW**

I conclude that the Respondent violated appropriate standards of care for the delivery of quality medical care to Patient A in violation of section 14-404(a)(22) of the Health Occupations Article of the Annotated Code of Maryland by conducting Patient A’s multiple plastic surgery procedures as a continuous operation lasting nine hours and thirty-seven minutes in an office-based surgery facility.

I also conclude that the Respondent violated appropriate standards of care for the delivery of quality medical care to Patient B in violation of section 14-404(a)(22) of the Health Occupations Article of the Annotated Code of Maryland by conducting Patient B's multiple plastic surgery procedures as a continuous operation lasting twelve hours and seven minutes in an office-based surgery facility.

I further conclude that the State has failed to prove that the Respondent violated appropriate standards of care for the delivery of quality medical care to Patient A in the management of Patient A's fluids.

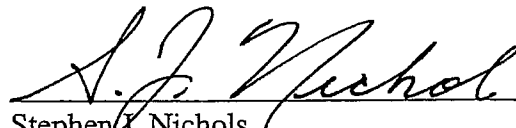
I further conclude that, as a result, the Board may discipline the Respondent and that an appropriate sanction would be to revoke the privilege of the Respondent to practice medicine in this State.

#### **PROPOSED DISPOSITION**

I **PROPOSE** that the charges filed by the Board on April 1, 2009, against the Respondent be **UPHELD** consistent with the conclusions of law, herein; and,

I further **PROPOSE** that as a sanction, the Respondent's privilege to practice medicine in this State be revoked.

November 17, 2010  
Date Decision Mailed  
#117338v1

  
Stephen J. Nichols  
Administrative Law Judge

## **NOTICE OF RIGHT TO FILE EXCEPTIONS**

Any party may file exceptions, in writing, to this Proposed Decision with the Board of Physicians within fifteen days of issuance of the decision. Md. Code Ann., State Gov't § 10-216 (2009) and COMAR 10.32.02.03F. The Office of Administrative Hearings is not a party to any review process.

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