

IN THE MATTER OF	*	BEFORE THE
EARL N. McLEOD, M.D.	*	STATE BOARD OF PHYSICIAN
Respondent	*	QUALITY ASSURANCE
License Number: D25792	*	Case Number: 98-0472
* * * * *		

CONSENT ORDER

On or about September 8, 1999, the Board of Physician Quality Assurance (the "Board") charged Earl N. McLeod, M.D. (the "Respondent") (D.O.B. 7/18/43), License Number D25792, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") § 14-404 (1994).

The pertinent provision of the Act under Health Occ. § 14-404 provides as follows:

- (a) Subject to the hearing provisions of § 14-405 of this subtitle, the Board, on the affirmative vote of a majority of its full authorized membership, 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.

Respondent, through his attorneys, Tydings and Rosenberg, L.L.P., Robert A. Gordon, Esquire, Paul Walter, Esquire, and Dawn L. Rubin, Assistant Attorney General, Administrative Prosecutor negotiated this proposed Consent Order for presentation to the Case Resolution Conference Committee of the Board on November 10, 1999.

FINDINGS OF FACT

1. At all times relevant to these charges, Respondent was and is a physician licensed to practice medicine in the State of Maryland. He was initially licensed in Maryland on October 23, 1980, and his license is presently active.
2. At the time of the acts described herein, Respondent was a physician engaged in the practice of Obstetrics and Gynecology at the Potomac Family Planning Center ("Center"), 966 Hungerford Drive, Rockville, Maryland 20850. At all times relevant to these charges, he was the owner and Medical Director of the Center, and the sole operating surgeon.
3. In 1992, Respondent decided to open the Center as a family planning clinic. The Center offers a full range of family planning services to women including abortion and gynecological services.
4. Prior to opening the Center, Respondent represents that he contacted the Maryland Department of Health and Mental Hygiene for guidelines governing freestanding abortion clinics and was told there were no guidelines.¹
5. Respondent represents that he purchased a sophisticated and expensive anesthesia delivery system from OHMEDA. This system included a medical vacuum gas pipeline system with manifolds in each surgical room and an integrated alarm system.
6. Respondent represents that he hired an anesthesiologist, who advised him as to equipping the facility for anesthesia and he advised Respondent to purchase, among other things, two pulse oximeters, an EKG machine, two portable automatic blood pressure cuffs, several

¹In August 1999, the Department of Health and Mental Hygiene promulgated regulations for freestanding ambulatory care facilities, at COMAR 10.05.01-05.

manual blood pressure cuffs and various medications to fit out a crash cart. The Respondent represents that he did so.

7. Respondent represents that he later hired Dr. K, also an anesthesiologist. Respondent represents that Dr. K told him that the anesthesia related equipment and supplies then available at the Center were satisfactory.
8. For staffing the recovery room, Respondent also hired a registered nurse with 15 years experience.
9. On or about December 22, 1997, the Board received a complaint from the Rockville Volunteer Fire Department alleging that on December 20, 1997, an unresponsive female patient had not been appropriately monitored after an outpatient surgical procedure, and the medical staff had failed to initiate appropriate resuscitation. The patient expired the next day.
10. On or about December 31, 1997, the Board opened a full investigation, and on or about July 10, 1998, as part of its investigation, referred the matter to the Peer Review Management Committee ("PRMC") of the Medical and Chirurgical Faculty of Maryland ("Med-Chi") for a review of the incident.
11. On or about July 13, 1998, the PRMC referred the case to the Montgomery County Medical Society ("Medical Society") for review. The Peer Review Committee of the Medical Society ("PRC") assigned two Board certified obstetrician-gynecologists ("peer reviewers") to review the case.
12. On or about October 9, 1998, the PRC submitted its report to the PRMC, concluding that the PRC and the peer reviewers concurred that although there was no breach in the

standard of care with respect to the operative procedure, Respondent did not meet the standard of care as the Medical Director of the Center with respect to the postoperative monitoring, treatment and resuscitation of Patient 1.² The PRMC submitted the report to the Board on or about October 22, 1998.

13. As a result of the PRC's report, the Board found probable cause to charge Respondent with a violation of § 14-404(a)(22) of the Act.

PATIENT 1

14. Patient 1 was a 27 year old female patient, who presented to the Potomac Family Planning Center on December 20, 1997, for an elective Dilatation and Curettage ("D&C") by Respondent for the purpose of terminating her pregnancy of six weeks. The patient did not have a significant medical or surgical history. She had undergone a previous termination of pregnancy in 1995 by Respondent, under general anesthesia without complication.
15. On the morning of December 20, 1997, Dr. K,³ an anesthesiologist, inserted an intravenous catheter ("IV") in Patient 1 in anticipation of general anesthesia. The patient was connected to a cardiac monitor, a blood pressure monitor and a pulse oximeter. Dr. K administered the following anesthetic medications: Midazolam (Versed) (used for preoperative sedation and memory impairment of perioperative events); Fentanyl (Sublimaze)(a narcotic agonist used for analgesic action of short duration during

²For purposes of patient confidentiality, the patient's name will not be used in this Consent Order.

³The Board also charged Dr. K with a violation of Health Occ. § 14-404(a)(22).

anesthesia); and Propofol (Diprivan)(IV sedative hypnotic agent used for the induction and maintenance of anesthesia or sedation) with Lidocaine. During the procedure, Patient 1 maintained spontaneous respirations, and did not require positive pressure ventilation. The procedure, approximately five minutes in duration, was completed by Respondent without incident.

16. After the procedure, Patient 1 was transferred to the Recovery Room at approximately 10:10 a.m.(according to the documentation), remained asleep, but was breathing spontaneously. The patient's blood pressure was documented as 112/60, and her heart rate as 103. Nurse W administered oxygen to her, by mask. The patient was not connected to a cardiac monitor, or pulse oximeter. After the patient's blood pressure was taken, another nurse (Nurse H) removed the cuff from the patient and placed it on another patient (when she arrived in the recovery room) where it remained for a period of time.
17. After Patient 1's transfer, Respondent began to perform a procedure on another patient in a second operating room.
18. At approximately 10:20 to 10:25 a.m., Nurse W, a recovery room nurse, noted that Patient 1 continued to remain unresponsive. Initially, she requested that the nursing assistant present in the recovery room, retrieve some "Zoloft" (an antidepressant) from the anesthesiologist, who was in the operating room with Respondent, but then changed her request to "Zofran" (an antiemetic). After her request, Nurse W went into the operating room herself to retrieve the Zofran from the anesthesiologist. The anesthesiologist provided the medication to Nurse W without evaluating Patient 1. There was no documentation in the record that the patient had experienced any nausea or vomiting.

19. According to the documentation, at approximately 10:25 a.m., Nurse W administered 2 cc of IV push Zofran to Patient 1. The patient remained unresponsive.
20. Shortly thereafter, Nurse W went back into the operating room to locate the anesthesiologist (who was in the room with Respondent), and requested another medication for Patient 1, Romazicon (reverses the sedative effects of benzodiazepines in cases where general anesthesia has been induced). The anesthesiologist gave permission to Nurse W to administer the Romazicon to Patient 1, again without evaluating her. Nurse W administered approximately 2cc of the medication IV push, to the patient, who continued to remain unresponsive.
21. Nurse H was replacing the blood pressure cuff on Patient 1, when she discovered she was pulseless, and her pupils were "dilated". She summonsed the anesthesiologist, who was still in the procedure room with another patient, to come evaluate the patient immediately. The anesthesiologist found the patient unresponsive, and the record reflects her blood pressure was 60/40. The anesthesiologist, Dr. K, started a second IV, and initiated cardio-pulmonary resuscitation. Initially, Dr. K ventilated the patient with a pediatric sized Bag Valve Mask ("BVM"), and then Nurse H took over, continuing to use the pediatric sized bag.
22. After completing two other procedures, Respondent entered the Recovery Room, and noticed that the staff was performing CPR on Patient 1. According to his statement, he helped administer IV medications. Also according to his statement, the patient was hooked up to an EKG monitor. Dr. K directed that the patient receive Epinephrine, Ephedrine and Lidocaine. There was no documentation of the patient's oxygen saturation

(patient was not hooked up to a pulse oximeter), any cardiac rhythm or any other aspects of a physical examination including any respiratory rate, chest/heart auscultation or neurological evaluation.

23. During this time, Respondent ordered that someone on his staff call 911, and this was done at approximately 10:42 a.m. The paramedics from the Rockville Volunteer Fire Department arrived shortly thereafter, and ascertained that the patient had suffered a cardiac arrest.
24. According to the paramedics, the anesthesiologist was unable to tell them what cardiac rhythm the patient was in. They discovered the patient was being ventilated with a pediatric BVM. The patient had not been intubated. The paramedics took control of the patient by intubating her, continuing resuscitation efforts with an adult BVM, hooking the patient to a cardiac monitor defibrillator, defibrillating her, and administering narcan,⁴ epinephrine and atropine IV push.
25. The paramedics transported the patient to Shady Grove Adventist Hospital by ambulance, and she arrived in the Emergency Room at approximately 11:09 a.m. On arrival, the attending physician in the ER noted that the patient's pupils were fixed and dilated, and there were no corneal reflexes noted. The ER staff carried out prolonged resuscitation efforts and eventually stabilized the patient's cardiac rhythm. The patient was transferred to the Intensive Care Unit. However, at approximately 4:15 a.m. on December 21st, Patient 1 expired.

⁴Narcan is a narcotic-agonist used in the reversal of narcotic-induced respiratory depression.

26. Respondent failed to meet the standard of care with regard to Patient 1 for reasons including the patient being inadequately monitored postoperatively in the recovery room by pulse oximetry, electrocardiogram, or blood pressure equipment. Further, as Medical Director, Respondent failed to ensure that there was adequate emergency equipment available to recovering patients including appropriate Ambu-bags or BVM, and endotracheal tubes that were readily accessible and in the appropriate size for intubation. As the sole operating surgeon and Medical Director of the Center, it was Respondent's responsibility to ensure adequate and safe postoperative care for Patient 1, and he failed to meet this standard.
27. Since December 20, 1997, Respondent has added two EKG machines, three automatic blood pressure cuffs and two pulse oximeters to the recovery room.

CONCLUSIONS OF LAW

Based upon the above Findings of Fact, the Board concludes as a matter of law, that Respondent failed to meet the appropriate standards as determined by appropriate peer review for the delivery of quality medical care in the State of Maryland, under Health Occ. § 14-404(a) (22) (1994).

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 17th day of November, 1999, by a majority of the full authorized membership of the Board considering this case:

ORDERED that Respondent's license to practice medicine be and is hereby **SUSPENDED**, for a period of three months from the date of this Consent Order; however, this **SUSPENSION** is hereby **STAYED** subject to his compliance with the terms and conditions of this Consent Order; and be it further

ORDERED that for a period of **THREE YEARS**, Respondent be subject to the following **TERMS AND CONDITIONS** of this **CONSENT ORDER**:

1. Respondent shall be monitored for a period of three years by the Compliance Unit of the Board of Physician Quality Assurance ("BPQA"). Such monitoring shall include but not be limited to random on-site inspections at the Board's discretion, and random requests for documentation such as patient logs, personnel staffing sheets and equipment inventory and servicing records. The monitoring shall include but not be limited to evaluating Respondent's compliance with the conditions listed in paragraphs (3) through (11) of this Order;
2. The results of the monitoring outlined in paragraph (1) shall be presented to the Board (through the Case Resolution Conference Committee or Weekly Review Panel) and noncompliance with any terms and conditions of this Consent Order shall be deemed a violation of this Order;

3. Within 30 days of the date of this Order, Respondent shall provide BPQA with a written inventory of monitoring and emergency equipment, and emergency medications (“inventory”), as outlined in paragraphs (4), (5) and (9). This inventory shall be presented to the Board (through the Case Resolution Conference Committee or Weekly Review Panel of the Board) for approval. The Board may add or modify Respondent’s inventory, and Respondent shall comply with the Board’s additions or modifications. Respondent’s failure to comply with such modifications shall be deemed a violation of this Consent Order;
4. Respondent shall ensure that in his capacity as Medical Director at Potomac Family Planning Center in Rockville, Maryland, or at any other family planning or ambulatory surgical center in the State of Maryland (hereinafter referred to as “facility”), that each and every patient receiving general anesthesia, conscious sedation, epidural or spinal anesthesia shall be monitored peri-operatively and post-operatively with equipment to include but not be limited to the following: a pulse oximeter, a cardiac monitor and a blood pressure monitoring device. The postoperative monitoring shall be continuous and remain as such for each patient until the Anesthesiologist determines that the patient is awake and alert;
5. Respondent shall ensure that in his capacity as Medical Director at a facility, that each and every patient undergoing a surgical procedure under local anesthesia shall be monitored pre-operatively and post-operatively with equipment to include but not be limited to the following: a blood pressure monitoring device;
6. Respondent shall document policies and procedures for the facility for anesthesia

care including coverage and monitoring and emergency protocols of anesthetized patients, and shall provide copies of these policies and procedures to the Board within 30 days of the date of this Order (through the Compliance Unit);

7. Respondent shall ensure that all health care personnel at the facility are certified by the American Heart Association in Basic Cardiac Life Support, and within 30 days of the date of this Order, shall provide written confirmation of staff certification to the Board (through the Compliance Unit);
8. Respondent shall ensure that there is adequate Anesthesiology coverage at the facility, and the Anesthesiologist shall perform the following duties: A licensed Anesthesiologist must be physically present in the operating room for each and every patient receiving general anesthesia during all phases of the procedure; physically transfer each and every patient who has received general anesthesia to the recovery room; provide report to the recovery room nurse as to the patient's condition; and remain in the recovery room with the patient until she is awake and alert. In the alternative, Respondent can arrange for there to be two licensed Anesthesiologists, or an Anesthesiologist and a licensed Certified Registered Nurse Anesthetist ("CRNA") to be present in the facility, with one being assigned to an operating room, and one being assigned to the recovery room. Under either option, every patient who receives general anesthesia will be monitored continuously by an Anesthesiologist or CRNA until awake and alert;
9. Respondent shall ensure that there will be the following monitoring and emergency equipment available in the facility:

- A. Mechanical ventilatory assistance to include Adult sized Ambu or Bag-Valve Masks (“BVM”) and nasal and oral airways in each operating room and in the recovery room;
 - B. Intubation equipment to include a laryngoscope and endotracheal tubes in each operating room, and in the recovery room;
 - C. Emergency medications in the operating rooms and recovery room as recommended and approved by the American Heart Association, the American Association of Ambulatory Health Centers (and approved by the Board);
 - D. A Cardiac Defibrillator that is easily accessible to staff;
 - E. Cardiac Monitoring equipment for each patient as outlined above in paragraph (4);
 - F. A Tracheostomy set;
 - G. Suction Equipment in each operating room, and in the recovery room;
 - H. Oxygen in the operating rooms and recovery room;
 - I. Pulse Oximeters as outlined above in paragraph (4); and
 - J. An emergency call system in the operating rooms and recovery room.
10. Respondent shall ensure that the equipment listed in paragraph (9) above shall be regularly checked by personnel in the facility to ensure optimal working condition, and that all medications listed in paragraph (9)(C) be checked regularly for

expiration,

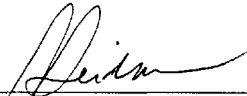
11. Respondent shall ensure that there is an adequate nursing to patient ratio in compliance with federal and State law, with a minimum of one licensed Registered Nurse on site when any patient is present in the facility; and it is further

ORDERED that:

12. Respondent shall not violate any other provision of the Maryland Medical Practice Act, or any other provision of State or Federal law;
13. In the event Respondent's becomes Medical Director of any other facility, or moves from his present address, Respondent shall immediately notify the Board in writing of either event, providing a new address and telephone number;
14. There shall be no early termination from the terms and conditions of this Consent Order. After three years from the date of this Consent Order, Respondent may petition the Board for termination of the terms and conditions imposed by this Consent Order. On successful completion of all terms and conditions imposed by this Consent Order, the Board shall terminate the terms and conditions imposed by this Consent Order. Should the Board terminate the terms and conditions of this Consent Order at that time, Respondent will continue to operate his facility or facilities within the terms and conditions set forth in this Consent Order (without the terms of direct supervision) as they apply to the Maryland Medical Practice Act, and any other provision of federal or State law;
15. Respondent's failure to comply with any of the terms or conditions of the Consent Order shall constitute a violation of the Consent Order; and it is further

16. **ORDERED** that Respondent shall be responsible for all reasonable and necessary costs incurred in fulfilling the conditions of this Consent Order; and it is further
17. **ORDERED** that this Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., State Gov't § 10-611, et seq. (1995);
18. If Respondent violates any of the terms or conditions of the Consent Order, after notice and a hearing, and a determination of the violation, the Board may impose any other disciplinary sanctions it deems appropriate, said violation of this Consent Order being proved by a preponderance of the evidence. If Respondent presents a danger to the public health, safety or welfare of the citizens of Maryland, the Board may summarily suspend Respondent's license under Md. Code Ann., State Gov't § 10-226 (c) (2) (1995).

11/12/95
Date




Sidney B. Seidman, M.D., Chair
State Board of Physician Quality Assurance


CONSENT OF EARL N. McLEOD, M.D.

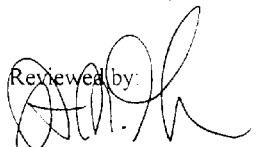
I, Earl N. McLeod, M.D., acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I admit to the Findings of Fact, and agree and accept to be bound by the foregoing Consent Order and its conditions and restrictions consisting of (12) pages. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

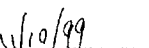
I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections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

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.


Earl N. McLeod, M.D.


Date

Reviewed by:

Robert A. Gordon, Esquire


Date

**STATE OF MARYLAND
CITY / COUNTY OF:**

I HEREBY CERTIFY that on this 10th day of November, 1999, before me, a Notary Public of the State and County aforesaid, personally appeared Earl N. McLeod, M.D., and oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS my hand and Notarial Seal.

Carol A. Palmer
Notary Public

My commission expires: 8/1/02