

1. The physician is certified or eligible for certification by the American Board of Obstetrics-Gynecology or the American Osteopathic Board of Obstetrics-Gynecology, and the physician satisfactorily completes at least 15 hours of Continuing Medical Education each year in obstetrics-gynecology.

2. The physician has admitting and surgical privileges at a nearby licensed hospital which has an operating room, blood bank, and an intensive care unit. The hospital shall be accessible within 20 minutes driving time during the usual hours of operation of the clinic.

3. The procedure shall be done in a location which is designated by the Department of Health as a licensed ambulatory care facility (LACF) authorized to perform surgical procedures as in subsection (e) above. The LACF shall be licensed by the Department of Health as an ambulatory care facility authorized to perform surgical procedures. The facility shall be in current and good standing at all times when surgical procedures are performed there. The LACF shall have a written agreement with an ambulance service assuring immediate transportation of a patient at all times when a patient has been admitted for surgery and until the patient has been discharged from the recovery room.

4. The procedure shall be done in an LACF which shall have a Medical Director and a Credentials Committee which have duly evaluated the training, experience and skill of the physician at continuous and successive levels of complexity of the D & E procedure in pregnancies advancing in stages from 18 weeks LMP through 19 weeks LMP through 20 weeks LMP, and the physician has been granted successive practice privileges consistent with management of the increased risk to the health and safety of the patient at that stage documented in the personnel file maintained for that physician. (Where the applicant physician is also the Medical Director, the physician shall submit a certificate from the Administrator or Chief of Department of a hospital or the Medical Director of an LACF where the applicant has been evaluated and credentialed in a comparable manner.) The physician new to the LACF shall have his or her operating technique evaluated initially and at least yearly by the Medical Director or his or her designee who shall possess appropriate experience with D & E procedures at least as advanced as those for which the applicant physician seeks approval. The applicant shall be evaluated during that number of procedures which shall be adequate to achieve a sufficient professional skill, and the evaluation procedure shall be documented in the personnel file maintained for that physician. The Medical Director shall agree to review the charts of all patients who suffer complications and in addition shall review charts at random, and shall calculate the complication rate of each physician.

5. The physician shall perform the procedure only on a patient who has been examined and found to be within

the eligibility criteria established for advanced D & E procedures in the LACF setting.

6. The procedure shall be performed in an LACF providing adequate staff support and resources for the operative procedure as well as interim follow-up and post-operative care, and where a physician is available and readily accessible 24 hours/day to respond to any postoperative problem.

7. The physician shall cooperate with the Medical Director to maintain contemporaneous and cumulative statistical records demonstrating the utilization and safety record of each stage procedure and of each surgeon. Said records shall be available for inspection by the Board and copies shall be submitted to the Board semi-annually. These records shall include the following information and data shall be maintained in records compiled monthly, but individual patients comprising the lists shall be identified only by date and by initials and/or case number:

- i. Number of patients who received termination procedures;
- ii. Number of patients who received laminaria or osmotic cervical dilators who failed to return for completion of the procedure;
- iii. Number of patients who reported for postoperative visits;
- iv. Number of patients who needed repeat procedures;
- v. Number of patients who received transfusions;
- vi. Number of patients suspected of perforation;
- vii. Number of patients who developed pelvic inflammatory disease within two weeks;
- viii. Number of patients who were admitted to a hospital within two weeks of the procedure;
- ix. Number of patients who died within 30 days.

Subparagraphs ii. through ix. above shall be summarized by number and percentage of monthly total for post-18 week procedures. The Board shall inspect such reports monthly for the first five months and at such further monthly intervals as it deems necessary.

(g) After 20 weeks: A physician may request from the Board permission to perform D & E procedures in an LACF after 20 weeks LMP. Such request shall be accompanied by proof, to the satisfaction of the Board, of superior training and experience as well as proof of support staff and facilities adequate to accommodate the increased risk to the patient of such procedure.

(h) The physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed

to make biologic and/or tissue disposals in accordance with law including rules of the Department of Health applicable to an LACF.

As amended, R.1984 d.470, effective October 15, 1984.  
Sec: 16 N.J.R. 2064(a), 16 N.J.R. 2823(a).

Section substantially amended.

Amended by R.1985 d.530, effective October 21, 1985.

Sec: 17 N.J.R. 1865(a), 17 N.J.R. 2562(b).

(e) recodified to (f) and new (e) added.

New Rule, R.1986 d.25, effective February 3, 1986.

Sec: 17 N.J.R. 2738(a), 18 N.J.R. 286(a).

Old rule repealed and new rule added.

Amended by R.1986 d.217, effective June 16, 1986.

Sec: 18 N.J.R. 614(a), 18 N.J.R. 1306(b).

Substantially amended.

Amended by R.1989 d.532, effective October 16, 1989.

Sec: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).

Deleted references to specific statutes and rules.

#### Case Notes

Preliminary injunction granted against regulation forbidding outpatient facility abortions after 18 weeks gestation or 20 weeks after last menstrual period; history of regulation; finding that plaintiffs likely to succeed in regulatory challenge due to regulation's possible result of causing women to forego their abortion rights if procedure medically acceptable on an outpatient basis is restricted to hospitals only (citing former regulation and previous codification as N.J.A.C. 13:35-7.2). *Pilgrim Medical Group v. New Jersey State Bd. of Medical Examiners*, 613 F.Supp. 837 (D.N.J.1985).

Former termination of pregnancy rule N.J.A.C. 13:35-7.2 upheld as properly adopted and reasonably related to maternal health; State has a compelling interest in maternal health after the first trimester of pregnancy so as to validate rules that foster that health. *Livingston v. New Jersey State Bd. of Medical Examiners*, 168 N.J.Super. 259, 402 A.2d 967 (App.Div.1979) certification denied 81 N.J. 406, 408 A.2d 800 (1979).

Physician's conduct in performing second trimester abortions was found not to constitute gross negligence, malpractice and incompetence; however, charges that physician's advertisements for safe, painless abortions were misleading were upheld. In the Matter of *Steven Chase Brigham*, 96 N.J.A.R.2d (BDS) 35.

### SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES, AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING

#### 13:35-4A.1 Purpose

These rules are designed to promote the health, safety and welfare of the members of the general public who undergo surgery (other than minor surgery), special procedures and receive anesthesia services in an office setting.

#### 13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting.

(b) For purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7, including the privileging standards set forth at (a) above, do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.

Amended by R.2002 d.404, effective December 16, 2002.

Sec: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

Rewrote the section.

#### 13:35-4A.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Advanced cardiac life support trained" means that a licensee has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (ALPS) is appropriate.

"Anesthesia services" means administration of any anesthetic agent with the purpose of creating conscious sedation, regional anesthesia or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia, minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

"Anesthesiologist" means a physician who has successfully completed a residency program in anesthesiology approved by the American Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who currently is a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

"Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating conscious sedation, regional anesthesia or general anesthesia.

"Anesthetizing location" means any location in an office where anesthetic agents are administered to a patient.

"Board" means the New Jersey State Board of Medical Examiners.

"Certified registered nurse anesthetist" (CRNA) means a registered professional nurse who is licensed in this State and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), and who meets the conditions for practice as a nurse anesthetist as set forth at N.J.A.C. 13:37-13.1.

“Complications” means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office setting including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

“Conscious sedation” means the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. For the purposes of this subchapter, conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Within the context of this subchapter, “conscious sedation” shall be synonymous with the term “sedation/analgesia” as used by the American Society of Anesthesiologists.

“General anesthesia” means the administration of a drug or drugs which cause loss of consciousness as the result of which the patient is unable to make meaningful responses but may still display reflex withdrawal from a painful stimulus.

“Health care personnel” means any office staff member who is licensed by a professional or health care occupational licensing board such as a professional registered nurse, licensed practical nurse or physician assistant.

“Hospital” means a hospital licensed by the state in which it is situated.

“Local anesthesia” means an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

“Minor conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks and ankle blocks. “Minor conduction block” does not include regional anesthesia that affects larger areas of the body, such as brachial plexus anesthesia or spinal anesthesia.

“Minor surgery” means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and subcutaneous tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic surgical procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as “major surgery” within the meaning of N.J.A.C. 13:35-4.1.

“Monitoring” means continuous visual observation of a patient and continuous observation of the patient using instruments to measure, display and record the values of certain physiologic variables such as pulse, oxygen saturation, blood pressure and respiration.

“Office” means a location at which medical, surgical or podiatric services are rendered and which contains only one operating room and which is not subject to the jurisdiction and licensure requirements of the New Jersey State Department of Health and Senior Services.

“Operating room” means that location in the office dedicated to the performance of surgery or special procedures.

“Pain management” means the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain. It includes the use or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transepidermal nerve stimulation (TENS), and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

“Pain medication” means, for the purpose of this subchapter, the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain occurring in the absence of an invasive, operative or manipulative procedure.

“Physical status classification” means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists enumerates classifications: I—Normal healthy patient; II—A patient with mild systemic disease; III—A patient with severe systemic disease limiting activity but not incapacitating; IV—A patient with incapacitating systemic disease that is a constant threat to life; and V—Moribund patients not expected to live 24 hours with or without operation.

“Physician” means an individual holding an M.D. or D.O. degree licensed pursuant to N.J.S.A. 45:9-1 et seq.

“Podiatrist” means an individual holding a D.P.M. degree licensed pursuant to N.J.S.A. 45:5-1 et seq.

“Practitioner” means a physician or a podiatrist.

“Privileges” means the authorization granted to a practitioner or physician by a hospital licensed in the jurisdiction in which it is located to provide specified services or alternatively by the Board pursuant to N.J.A.C. 13:35-4.12, such as surgery or the administration or the supervision of administration of one or more types of anesthetic agents or procedures.

“Recovery area” means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

“Regional anesthesia” means the administration of anesthetic agents to a patient to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal and brachial anesthesia. Regional anesthesia does not include minor conduction blocks as defined in this section.

“Special procedure” means patient care which requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile, for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing conscious sedation or general anesthesia; invasive radiologic procedures performed utilizing conscious sedation; pediatric magnetic resonance imaging performed utilizing conscious sedation; or manipulation under anesthesia (MUA). The term special procedure does not include a procedure which only requires medication to reduce anxiety such as oral benzodiazepine unless the dose given is intended to provide conscious sedation.

“Supervision” means responsibility by a credentialed physician who is immediately available to oversee the administration and monitoring of anesthesia by health care personnel authorized by this rule to render anesthesia services in an office.

“Surgery” means a manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering. Surgery includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture or extraction of tissue from the uterus.

“Topical anesthesia” means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

Amended by R.2002 d.404, effective December 16, 2002.

See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

Rewrote the section.

### 13:35-4A.4 Policies and procedures requirements

(a) Practitioners who perform surgery (other than minor surgery) or special procedures and physicians who administer or supervise the administration or monitoring of anesthesia services in an office shall establish written policies and procedures concerning the following:

1. The specific surgical or special procedures which may be performed in the office;
2. The specific anesthesia services which may be performed in the office;
3. The responsibilities of the health care personnel providing services to patients in the office;
4. The infection control practices to be followed, including lawful disposal of hazardous waste;
5. The procedures to be followed in the event that a patient experiences a complication;
6. The procedures to be followed if the patient requires transport for emergency services, including the identity and telephone numbers of the ambulance service if one is to be utilized and the hospital to which the patient is to be transported, and the functions to be undertaken by health care personnel until a transfer of the patient is completed;
7. The procedures to be followed in the event that a surgery or special procedure needs to be terminated because of an equipment malfunction or other complication;
8. The procedures to be followed while a patient is recovering in the office;
9. The objective criteria for discharging patients; and
10. The procedures to be followed to review records, and to ensure follow-up on complications and outcomes.

(b) The written policies and procedures shall also contain the identity of the specific practitioners within the office who are responsible for ensuring that:

1. All healthcare personnel providing services to patients possess the qualifications required by this subchapter and are currently licensed, registered or certified, as applicable;
2. All equipment and instruments utilized in the performance of surgery are maintained in proper working order and in accordance with such sterilization techniques as are required for safe medical practice;
3. All equipment and safety systems utilized in the administration and monitoring of anesthesia as required by N.J.A.C. 13:35-4A.14 are maintained in proper working order;
4. All emergency equipment and supplies as required by N.J.A.C. 13:35-4A.13 are available and are not outdated; and
5. All medical records are audited on at least an annual basis to assess quality of care and complications.

(c) The written policies and procedures are to be reviewed annually and revised as needed with the person conducting the review or making the revision recording the date thereof.

(d) Written policies and procedures shall be presented to the Board upon request.

**13:35-4A.5 Duty to report incidents related to surgery, special procedures or anesthesia in an office**

Any incident related to surgery, special procedures or the administration of anesthesia within the office which results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication or untoward event as defined in N.J.A.C. 13:35-4A.3, shall be reported to the Executive Director of the Board within seven days, in writing and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. 45:9-19.3.

**13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge**

(a) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall be privileged to perform that surgery or special procedure by a hospital. If a practitioner is not privileged but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) Before any practitioner may perform surgery (other than minor surgery), or special procedures, the practitioner shall have:

1. A written transfer agreement with a licensed hospital with acute care capabilities which can be reached within 20 minutes during all hours in which surgery or special procedures are performed in the office, if the hospital where the practitioner is privileged is not reachable within 20 minutes or if the practitioner is privileged by the Board; and
2. A written policy for handling emergency transport to a hospital at which the practitioner is privileged through 9-1-1 call or a written transfer agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital which the practitioner has established a transfer agreement. The written transfer agreement shall be posted in the office and all health care personnel in the office shall specifically be informed of the procedure to be followed.

(c) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall provide pre-procedure counseling and preparation as follows:

1. The practitioner shall appropriately assess, or review a referring physician's assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure. Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2. A history and physical examination shall be performed within the 14 days preceding the proposed surgery either by the practitioner performing the surgery or procedure (as appropriate to that practitioner's scope of practice) or by another physician or physician assistant under the supervision of a physician. Necessary laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;

3. The risks and benefits of the surgery or special procedure and alternative methods or treatments shall be fully explained by the practitioner or other health care personnel, and written informed consent for the specific surgery or special procedure contemplated shall be obtained from the patient, guardian or authorized representative;

4. An appropriate fasting protocol shall be explained and provided to the patient;

5. If the history and physical are not done on the same day as the procedure, an interim assessment shall be performed by the practitioner or a physician assistant under the supervision of a physician immediately prior to the procedure, which assessment shall be documented and dated; and

6. Prior to surgery, the practitioner shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.

(d) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall ensure the following during recovery and prior to discharge:

1. Immediately after the surgery or special procedure, the patient shall be evaluated by either the practitioner who performed the surgery or the physician or CRNA who administered the anesthesia;

2. At least one practitioner shall remain on the premises until the patient is discharged from the recovery area;

3. The patient shall be provided with written and verbal instructions for follow-up care and with advice concerning possible complications; and

4. The patient shall be discharged into the company of a responsible individual.

(e) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall prepare a patient record which shall include the following:

1. A pre-procedure medical history and physical, appropriate to the practitioner's scope of practice, including such data as allergies, physical and mental impairments, vital signs, drug use, mobility limitations and, as applicable, electrocardiogram results, radiologic findings, laboratory values and the identity of the examining practitioner;

2. Documentation reflecting that informed consent has been obtained;

3. A description of the surgery or special procedure performed, including pre-operative diagnosis, techniques used, names and titles of medical personnel participating, complete findings, post-operative diagnosis, and any unusual occurrence, complications or untoward events. Where similar procedures are performed at the office routinely, partially pre-printed forms may be utilized as a guide, provided that original data and conclusions applicable to the specific patient are contemporaneously entered to create a complete report;

4. A post-procedure note, entered prior to discharge from the office, which shall include at least such post-procedure data as the patient's general condition, vital signs, any treatments ordered, and all drugs prescribed, administered or dispensed including dosages, quantities and strengths;

5. The identity of healthcare personnel providing services, as evidenced by a legible signature following that staff member's notation in the patient's record; and

6. The plan for follow-up care and documentation of results of follow-up efforts.

(f) No practitioner who performs surgery (other than minor surgery) or special procedures in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or

2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

Public Notice: Suspension of enforcement.

See: 30 N.J.R. 4485(b).

Amended by R.2002 d.404, effective December 16, 2002.

See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

Rewrote the section.

**13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient**

(a) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall be privileged by a hospital to provide the particular anesthesia service. If a practitioner is not privileged but wishes to administer or supervise the administration of anesthesia services, the physician shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2. A medical history shall be conducted including a review of abnormalities in any organ system; previous adverse experience with anesthesia services; any history of stridor, snoring or sleep apnea, or of advanced rheumatoid arthritis or spinal disorder; current medications being taken; drug allergies; or any history of substance abuse;

3. The risks and benefits of anesthesia and alternative methods or treatments shall be fully explained by the physician or certified registered nurse anesthetist (CRNA), and written informed consent for the anesthesia services contemplated shall be obtained from the patient, guardian or authorized representative;

4. An appropriate fasting protocol shall be explained and timely provided to the patient, guardian or authorized representative;

5. Pre-procedure laboratory test results shall be reviewed and recorded;

6. A focused physical examination shall be conducted, including auscultation of the heart and lungs, and an evaluation of the airway, particularly an assessment of anatomical abnormalities (that is, jaw, mouth, head and neck) which may increase the likelihood of an airway obstruction;

7. A plan of anesthesia shall be developed by the physician administering anesthesia services or personally reviewed by the supervising physician if the plan has been developed by other authorized personnel;

8. A patient shall be counseled prior to the procedure that the procedure will be canceled if the patient plans to drive home after the procedure and has not made arrangements to be accompanied home by an individual who accepts responsibility for the patient; and

9. Prior to the administration of anesthesia services, the physician shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.

(c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia or conscious sedation) in an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

1. Direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;

2. Pulse oximetry shall be performed continuously. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness;

3. An electrocardiogram monitor shall be used continuously on the patient;

4. The patient's blood pressure, pulse rate, and respirations shall be measured at least every five minutes; and

5. The body temperature of a pediatric patient shall be measured continuously.

(d) In addition to the monitoring requirements in (c) above, a physician who administers or supervises the administration or monitoring of general anesthesia services in an office shall ensure that additional monitoring is provided as follows:

1. End-tidal carbon dioxide monitoring shall be performed on the patient continuously during endotracheal anesthesia;

2. An in-circuit oxygen analyzer shall be used to monitor the oxygen concentration within the breathing circuit, displaying the oxygen percent of the total inspiratory mixture;

3. A respirometer (volumeter) shall be used to measure exhaled tidal volume whenever the breathing circuit of a patient allows;

4. The body temperature of each patient shall be measured continuously; and

5. An esophageal or precordial stethoscope shall be available and utilized on the patient when indicated.

(e) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall establish within that office a recovery area and ensure that recovery services are provided as follows:

1. Immediately after the surgery or special procedure, the practitioner who performed the surgery or the individual who administered the anesthesia shall evaluate the patient;

2. The individual responsible for the administration or monitoring of anesthesia shall accompany the patient into the recovery area;

3. Healthcare personnel who were present with the patient at the anesthetizing location shall remain with the patient in the recovery area at least until the patient's vital signs, including blood pressure, pulse, and respiration are recorded;

4. An oral report on the patient's condition shall be given to any healthcare personnel in the recovery area not present in the anesthetizing location;

5. Whenever a patient is present in the recovery area, the recovery area shall be staffed by at least one registered professional nurse or physician assistant who is trained and experienced in advanced cardiac life support and post anesthesia care. This includes recognizing the actions and interactions of anesthetic techniques, manag-

ing of airway and ventilatory function and managing patients during altered states of consciousness, as well as cardiopulmonary resuscitation, monitoring of cardiac function, recognition of arrhythmias, and the recognition and treatment of life-threatening emergencies. For every additional two patients present in the recovery area, there shall be one additional professional registered nurse or physician assistant present, having the requisite training;

6. In addition to the healthcare personnel specified in (e)5 above, at least one other additional healthcare personnel shall remain on site in a position to render immediate assistance whenever a patient is in the recovery room; and

7. From the time of entry into the recovery area until discharge, the condition of the patient shall be regularly evaluated and the patient's vital signs checked at least every five minutes. If the patient's vital signs remain unchanged, documentation can be reflected with a straight line on the chart; any changes shall be specifically noted. Electrocardiographic monitoring and pulse oximetry monitoring shall be continued in the recovery area for each patient who has received anesthesia services.

(f) A practitioner who administers or supervises the administration and monitoring of anesthesia services may allow a patient dischargeable to home pursuant to N.J.A.C. 13:35-4A.4(a)9 and 4A.6(d) to remain in the office for a period not to exceed 23 hours in an overstay area, if the patient may benefit from additional care. The overstay area shall be staffed by at least one registered professional nurse or physician assistant for each two patients in the overstay area, the patient's vital signs shall be taken and recorded at least every four hours and a physician shall be able to reach the office within 20 minutes. Appropriate sleeping accommodations, as well as food, shall be provided for the patient.

(g) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure the following prior to discharge:

1. That at least one practitioner shall remain on the premises until the patient is discharged to home or transferred to the special overnight stay area;
2. That the patient shall be given written and verbal instructions for follow-up care and advice concerning complications;
3. That before the patient leaves the office or is transferred to the overstay area, the physician shall evaluate the patient and shall review and sign the post-anesthesia record; and
4. That the patient shall be discharged only into the company of a responsible individual.

(h) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure that a patient record is prepared which contains the following:

1. A pre-anesthesia note, including pre-anesthesia vital signs (blood pressure, temperature, respiration rate and pulse), and a plan of anesthesia;
2. Signed informed consent from the patient, guardian or authorized representative;
3. An intra-procedure record which includes anesthetic agents and techniques used, any changes since the inception of anesthesia in vital signs, oxygen saturation, electrocardiogram interpretation, temperature and end-tidal carbon dioxide measurements when required, as well as the volume and type of fluids administered;
4. A post-anesthesia note entered prior to the patient's discharge from the office which shall include at least such post-procedure data as the patient's vital signs and general condition, respiration, consciousness, circulation, special problems or precautions and a summary of fluids received during surgery or any complication or untoward event which occurred;
5. The identity of each healthcare personnel providing services, as evidenced by the staff member's legible signature on each entry made by that staff member in the patient record; and
6. The plan for follow-up care.

(i) No practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or
2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

Public Notice: Suspension of enforcement.

See: 30 N.J.R. 4485(b).

Amended by R.2002 d.404, effective December 16, 2002.

See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

Rewrote the section.

### **13:35-4A.8 Performance of general anesthesia; authorized personnel**

(a) General anesthesia shall be administered and monitored in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide general anesthesia services and who, during every consecutive three-year period beginning July 1, 2004, completes at least 60 Category I hours of continuing medical education in anesthesia which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

(b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of conscious sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.

(c) When the administration and monitoring of general anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.

(d) An advanced cardiac life support-trained physician, registered professional nurse or physician assistant shall remain with the patient at all times that the patient is receiving or recovering from general anesthesia.

Public Notice: Suspension of enforcement.

Sec: 30 N.J.R. 4485(b).

Amended by R.2002 d.404, effective December 16, 2002.

Sec: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

In (a), rewrote 1 and substituted "qualified" for "eligible" in 2; in (b), added the second sentence.

#### **13:35-4A.9 Administration of regional anesthesia; authorized personnel**

(a) Regional anesthesia shall be administered and monitored in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide regional anesthesia and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I hours of continuing medical education in anesthesia exclusively, or in anesthesia as it relates to the

physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

(b) The administration and monitoring of regional anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or the special procedure.

(c) When the administration and monitoring of regional anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.

(d) An advanced cardiac life support trained physician, registered professional nurse or physician assistant shall be present at all times when a patient is receiving or recovering from regional anesthesia.

Public Notice: Suspension of enforcement.

Sec: 30 N.J.R. 4485(b).

Amended by R.2002 d.404, effective December 16, 2002.

Sec: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

In (a), rewrote 1 and substituted "qualified" for "eligible" in 2.

#### **13:35-4A.10 Administration of conscious sedation; authorized personnel**

(a) Conscious sedation shall be administered in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide conscious sedation and who, during every consecutive three-year period beginning July 1, 2001, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including conscious sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above; or

3. A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of conscious sedation which was selected and initially admin-

istered by the physician who remains continuously present in the procedure room. "Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.

(b) A patient under conscious sedation shall be monitored in an office by a physician, CRNA, or a registered professional nurse or physician assistant who has training and experience in the use of monitoring devices, under the supervision of a physician eligible under (a)1 above, to administer conscious sedation.

(c) The monitoring of a patient under conscious sedation shall be provided by an individual who meets the requirements of (b) above and who is at all times present and who is not the practitioner who is performing the surgery or special procedure.

(d) When the administration and monitoring of conscious sedation is being performed by a CRNA, or when the monitoring is being performed by a registered professional nurse or physician assistant, the supervising physician shall be physically present, but may be concurrently responsible for patient care.

(e) An advanced cardiac life support-trained physician, registered nurse or physician assistant shall be present at all times when a patient is receiving or recovering from the administration of conscious sedation.

Public Notice: Suspension of enforcement.

See: 30 N.J.R. 4485(b).

Amended by R.2002 d.404, effective December 16, 2002.

See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

In (a), rewrote 1, substituted "qualified" for "eligible" in 2, inserted "and monitoring" preceding "of anesthetic" and substituted "qualified" for "eligible" in 3.

#### **13:35-4A.11 Administration of minor conduction blocks; authorized personnel**

(a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:

1. A practitioner;
2. A certified registered nurse anesthetist (CRNA); or
3. A certified nurse midwife, an advanced practice nurse or physician assistant who has training and experience in the administration of minor conduction blocks.

(b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital or by the Board pursuant to N.J.A.C. 13:35-4A.12.

Amended by R.2002 d.404, effective December 16, 2002.

See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).

In (a), inserted "with the exception of retrobulbar blocks" following "blocks" and deleted "other than minor surgery" in the introductory paragraph, and substituted "an advanced practice nurse" for "a nurse practitioner, clinical nurse specialist" in 3; rewrote (b).

#### **13:35-4A.12 Alternative privileging procedure**

(a) A practitioner who seeks to provide or supervise the administration and monitoring of general or regional anesthesia, as well as conscious sedation, in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number of procedures for which general or regional anesthesia was provided by the applicant in the last two years for all age groups of patients within the applicant's practice for which privileges are requested;

2. Any one of the following:

- i. Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity that the applicant demonstrates has standards of comparable rigor;

- ii. Successful completion of a residency training program in anesthesiology accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA); or

- iii. Supervised training in residency, fellowship or other equivalent experience in another field and active participation in the examination process leading to certification in anesthesiology; and

3. Possess clinical competence to perform the anesthesia services or procedures authorized by the requested privileges, with such competence confirmed by the following:

- i. Three references submitted directly by plenary licensed physicians addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;

- ii. Submission of a log listing all patients for whom the applicant provided any of the anesthesia services in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the type of anesthesia service provided, the surgery or special procedure performed and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;