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.
See: 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.
See: 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.
See: 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.
See: 18 N.J.R. 614(a), 18 N.J.R. 1306(b).
Substantially amended.
Amended by R.1989 d.532, effective October 16, 1989.
See: 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.
See: 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.