(d) The Board in its discretion may waive any or all of the required subjects if the credentials presented include proof of a score of 80 on each part of the Federation Licensing Examination or the Uniform State Medical Licensing Examination.

(e) If the Board identifies substantive deficiencies, and none of the credentials identified at (b), (c) or (d) above have been presented, the applicant may be provided leave to secure such credentials and the Board, upon request, may provide guidance to applicants seeking to remediate deficiencies.

New Rule, R.1994 d.539, effective November 7, 1994.
See: 26 N.J.R. 2742(b), 26 N.J.R. 4418(a).

13:35–3.13 Criminal history record information

The Board shall require a criminal history record check by the Division of State Police of all applicants for initial licensure to practice medicine and surgery in this State. Such criminal history record checks shall be obtained, processed and maintained in accordance with the procedures established by the Division of State Police pursuant to P.L. 1994, c.60 (N.J.S.A. 53:1–20.5 et seq.) and N.J.A.C. 13:59. Such criminal history records shall be disseminated in strict accordance with the limitations established by the Division of State Police pursuant to N.J.A.C. 13:59–1.6 and are not public records within the meaning of the Right to Know Law, P.L. 1963, c.73 (N.J.S.A. 47:1A–1 et seq.). Fees for criminal history record checks shall be paid by applicants for licensure in conformity with P.L. 1994, c.60 (N.J.S.A. 53:1–7) and N.J.A.C. 13:59–1.3 and 1.4. In addition to its use in evaluating an application for initial licensure, the Board may obtain criminal history record information from the Division of State Police for any other purpose authorized by statute or regulation.

New Rule, R.1995 d.554, effective October 16, 1995.
See: 27 N.J.R. 1743(a), 27 N.J.R. 3964(a).

SUBCHAPTER 4. SURGERY

13:35–4.1 Major surgery; qualified first assistant

(a) A major surgical procedure is one with a substantial hazard to the life, health or welfare of a patient. By way of example, but not limitation, a major surgical procedure includes:

1. A procedure in which an opening is made into any of the three major body cavities (abdomen, chest or head), exclusive of endoscopic approaches which explore existing channels and involve no transverse of a body wall (for example, bronchoscopy, colonoscopy) or are exclusively diagnostic (for example, laparoscopy, colposcopy). With respect to non-diagnostic endoscopic procedures requiring the transverse of a body wall, a duly qualified first assistant shall be immediately available in the operating suite;

2. A procedure performing a major amputation;

3. A procedure performed where the locality, the condition, the difficulty or the length of time required to operate would constitute a direct hazard to the life of the patient.

(b) A major surgical procedure shall be performed by a duly qualified surgeon with a duly qualified assisting physician who may be a duly qualified resident in or rotating through a training program approved by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

(c) In addition to those individuals listed in (b) above who may act as qualified first assistants, in a health care facility licensed by the Department of Health, a duly qualified registered nurse first assistant (RNFA) or a duly qualified physician assistant may so act.

(d) A duly qualified surgeon, duly qualified assistant physician, duly qualified resident, duly qualified registered nurse first assistant or duly qualified physician assistant shall be determined by the hospital credentials committee in conjunction with the chairman or chief of the appropriate committee in conjunction with the chairman or chief of the appropriate department or division consistent with the requirements of law or applicable rule.

(e) It shall be the responsibility of each medical staff to promulgate appropriate rules to fully and carefully implement the requirements of (b), (c), and (d) above by determining which procedures shall be considered major surgery in accordance with (a) above, and determining the credentials of each individual qualified to act as first assistant for any given major surgical procedure. The medical staff and hospital board of trustees shall assure compliance by the individual first assistants with this rule of the Board and the rules of the hospital or other facility licensed by the Department of Health.

(f) In all instances in which a registered nurse first assistant or a physician assistant may act as first assistant pursuant to (c) above, the operating surgeon shall have discretion to determine whether to utilize such an individual as a first assistant, despite the fact that they are permitted to so act pursuant to this rule.

(g) In the event of incapacity or unavailability of the operating surgeon during a major surgical procedure, the functions of a first assistant who is not a physician shall be limited to maintaining the status of the patient while a substitute operating surgeon is summoned, except in matters of dire emergency. "Dire emergency" shall include only those circumstances posing a significant risk of imminent death or serious bodily injury to the patient, such as uncontrolled bleeding.

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Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).
Amended by R.1995 d.503, effective September 5, 1995.
See: 27 N.J.R. 1744(a), 27 N.J.R. 3365(a).

Cross References

Physician assistant, assisting surgery, see N.J.A.C. 13:35–6.15.

Case Notes

Validity of rule (dissenting opinion). Eatough v. Albano, 673 F.2d 671 (1982) certiorari denied 102 S.Ct. 2931, 457 U.S. 1119, 73 L.Ed.2d 1331.

License revocation for violation of Medical Practice Act upheld; no denial of due process; Board could only impose monetary penalty for each statutory provision violated; additional penalties for multiple violations of each provision improper where physicians had no prior convictions for such offenses. In re Suspension of License of Wolfe, 160 N.J.Super. 114, 388 A.2d 1316 (App.Div.1978) certification denied 78 N.J. 406, 396 A.2d 592 (1978).

Former N.J.A.C. 13:35–7.1 governing the conduct of major surgery upheld as not inconsistent with the Medical Practice Act and as neither arbitrary, capricious, unreasonable nor vague. Garden State Community Hospital v. State Bd. of Medical Examiners, 147 N.J.Super. 592, 371 A.2d 794 (App.Div.1977) certification denied 74 N.J. 283, 377 A.2d 688 (1977).

13:35–4.2 Termination of pregnancy

(a) This rule is intended to regulate the quality of medical care offered by licensed physicians for the protection of the public, and is not intended to affect rules of the Department of Health establishing institutional requirements. To the extent that rules of the two agencies may overlap, the Medical Board recognizes and relies upon the regulatory procedures of the Department of Health in establishing minimum acceptable standards for non-physician personnel, equipment and resources, the adequacy of the physical plant of the facility in which surgical procedures shall be performed, and the facility's interrelationship with an adequate network of health care-related resources such as ambulance service, etc.

(b) The termination of a pregnancy at any stage of gestation is a procedure which may be performed only by a physician licensed to practice medicine and surgery in the State of New Jersey.

(c) Provisions of this rule referring to stage of pregnancy shall be in terms of weeks from start of last menstrual period or "weeks LMP." For example, the stage of pregnancy at 12 weeks' gestational size, as determined by a physician, is the equivalent of 14 weeks from the first day of the last menstrual period (LMP).

(d) After 14 weeks LMP, any termination procedure other than dilatation and evacuation (D & E) shall be performed only in a licensed hospital.

(e) Fifteen weeks through 18 weeks LMP: After 14 weeks LMP and through 18 weeks LMP, a D & E procedure may be performed either in a licensed hospital or in a licensed ambulatory care facility (referred to herein as LACF) authorized to perform surgical procedures by the Department of Health. The physician may perform the procedure in an LACF which shall have a Medical Director who shall chair a Credentials Committee. The Committee shall grant to operating physicians practice privileges relating to the complexity of the procedure and commensurate with an assessment of the training, experience and skills of each physician for the health, safety and welfare of the public. A list of the privileges of each physician shall contain the effective date of each privilege conferred, shall be reviewed at least biennially, and shall be preserved in the files of the LACF.

(f) Nineteen weeks through 20 weeks LMP: A physician planning to perform a D & E procedure after 18 weeks LMP and through 20 weeks LMP in an LACF shall first file with the Board a certification signed by the Medical Director that the physician meets the eligibility standards set forth in (f)1 through 7 below and shall comply with its requirements.

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 postoperative 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).

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

13:35–5.1 Minimum eye examination; contact lenses

(a) Physicians licensed to practice medicine and surgery, when performing an eye examination for the purpose of prescribing corrective lenses, shall fully and adequately disclose to the patient the limited purpose of the eye examination. The physician shall perform, and keep a complete record of, physical examination of the patient which shall include:

1. A complete history of visual aberrations;

2. A determination of visual acuity in each eye separately;

3. A cover test, distance and near, and a determination of muscle balance or imbalance;

4. An ophthalmoscopic examination and a determination of any abnormalities of lids, cornea, pupils, lens, vitreous and fundus. A record entry of "negative" or "clear" should be made if no pathology is found.

(b) Upon observing positive findings of ocular disease or abnormality, the physician shall disclose his findings to the patient and suggest an appropriate course of action.

(c) The complete record of contact lens specifications shall be released by an ophthalmologist to another ophthalmologist, optometrist or ophthalmic dispenser licensed in New Jersey upon either the oral or written request of the patient or the professional acting on the patient's behalf.

13:35–5.2 Minimum standards and tolerances of optical lenses

(a) Every pair of lenses, spectacles, eyeglasses or appurtenances thereto, prepared for or dispensed to the intended wearers from written prescriptions of physicians duly licensed to practice their profession, or duplication, replacements, reproductions or repetitions, must conform to the following minimum standards and tolerances:

PHYSICAL QUALITY AND APPEARANCE

1. Surface imperfections

TOLERANCE: No pits, scratches (other than hairline), grayness or watermarks shall be acceptable.

2. Glass defects

TOLERANCE: No bubbles, striae and inclusions shall be acceptable.

3. Localized power errors

TOLERANCE: Waves found by visual inspection shall be passable if no deterioration in image quality is found when the localized area is examined with a standard lens measuring instrument.

4. Refractive powers

TOLERANCE: 0.0. to 6.00, + or −0.12.

6.25 to 12.00, 2 per cent of power.

Above 12.00, + or −0.25.

Maximum cylinder power variation + or −0.12.

5. Refractive power addition

TOLERANCE: + or −0.12.0.

6. Cylinder Axis

TOLERANCE: 0.12 to 0.37 + or −3 degrees.

0.50 to 1.00, + or −2 degrees.

1.12 on up, + or −1 degree.

7. Prism power and location of specified optical center

TOLERANCE: Vertical + or −0.25 prism for each lens or a total of 0.50 prism imbalance. Horizontal + or −0.25 prism for each lens or a total of 0.50 prism imbalance.

8. Segment size

TOLERANCE: + or −0.5 mm. Pair must be symmetrical upon visual inspection.

9. Segment location

TOLERANCE: As specified within + or −0.5 mm.

10. Lens size:

i. Rimless

TOLERANCE: + or −0.5 mm;

ii. Bevel, for plastic frames

TOLERANCE: + or −0.5 mm;

iii. Bevel, for metal frames

TOLERANCE: To fit standard specified frame. Lens shape must match. Edges must be smooth and straight and sharp edge must be removed.