CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES

Authority

N.J.S.A. 26:2H–5 and 26:2H–8

Source and Effective Date

R.2002 d.142, effective May 20, 2002.
See: 33 N.J.R. 2619(a), 34 N.J.R. 1831(b).

Chapter Expiration Date

Chapter 43A, Manual Standards for Licensing of Ambulatory Care Facilities, expires on May 20, 2007.

Chapter Historical Note

Chapter 43A, Ambulatory Care Facilities, was adopted as R.1976 d.165, effective May 26, 1976. See: 8 N.J.R. 117(a), 8 N.J.R. 282(b).

The expiration date for Subchapter 14 was extended by R.1979 d.489, effective December 14, 1979. See: 11 N.J.R. 547(a), 12 N.J.R. 16(b).

The expiration date for Subchapter 14 was further extended by R.1980 d.273. See: 12 N.J.R. 407(c).

Pursuant to Executive Order 66(1978), Chapter 43A, Ambulatory Care Facilities, was readopted as R.1983 d.427, effective October 3, 1983. See: 15 N.J.R. 994(a), 15 N.J.R. 1662(a).

Pursuant to Executive Order No. 66(1978), Chapter 43A, Ambulatory Care Facilities, was readopted as R.1984 d.497, filed October 18, 1984. See: 16 N.J.R. 2208(a), 16 N.J.R. 3031(a).

Chapter 43A, Ambulatory Care Facilities, was repealed and Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was adopted as new rules by R.1985 d.438, effective September 3, 1985. See: 16 N.J.R. 3254(a), 17 N.J.R. 2110(b).

Petition for Rulemaking. See: 19 N.J.R. 306(d), 19 N.J.R. 570(b).

Pursuant to Executive Order No. 66 (1978), Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was readopted as R.1990 d.416, effective July 27, 1990. See: 22 N.J.R. 1496(a), 22 N.J.R. 2507(a).

Pursuant to Executive Order No. 66 (1978), Chapter 43A, Manual of Standards for Licensure of Ambulatory Care Facilities, was readopted as R.1993 d.443, effective August 16, 1993, and Subchapters 1 through 11 and 13 through 19 were repealed and new Subchapters 1 through 11 and 13 through 29 were adopted by R.1993 d.443, effective September 7, 1993. See: 25 N.J.R. 757(b), 25 N.J.R. 4140(a).

Pursuant to Executive Order No. 66(1978), Chapter 43A, Manual of Standards for Licensure of Ambulatory Care Facilities, expired on August 16, 1998.

Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was adopted as new rules by R.1998 d.535, effective November 16, 1998. See: 30 N.J.R. 2558(a), 30 N.J.R. 4070(c).

Administrative correction. See: 31 N.J.R. 54(a).

Subchapter 30, Radiation Oncology, was adopted as new rules by R.2000 d.376, effective September 18, 2000. See. 31 N.J.R. 2729(a), 32 N.J.R. 3459(b).

Chapter 43A, Manual of Standards for Licensure of Ambulatory Care Facilities, expired on November 16, 2001.

Chapter 43A, Manual of Standards for Licensing of Ambulatory Care Facilities, was adopted as new rules by R.2002 d.142, effective May 20, 2002. See: Source and Effective Date.

Administrative correction. See: 34 N.J.R. 3022(a).

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SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

8:43A–1.1 Scope

The rules in this chapter pertain to all health care facilities which provide ambulatory care services including, but not limited to, primary care, hospital outpatient, ambulatory surgery, family practice, family planning, outpatient drug abuse treatment, chronic dialysis, computerized tomography, magnetic resonance imaging, extracorporeal shock wave lithotripsy, and radiological services. These rules also pertain to abortion facilities, comprehensive outpatient rehabilitation facilities, and birth centers. Ambulatory care facilities provide preventive, diagnostic, and treatment services to persons who come to the facility to receive services and

depart from the facility on the same day. The rules in this chapter constitute the basis for the licensure of ambulatory care facilities by the New Jersey State Department of Health.

8:43A–1.2 Purpose

The goal of this chapter is to protect the health and safety of patients who receive ambulatory care services by establishing minimum rules and standards of care with which an ambulatory care facility must comply in order to be licensed to operate in New Jersey.

8:43A–1.3 Definitions

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

"Abortion facility" means a facility which performs termination of pregnancy, in accordance with N.J.A.C. 13:35–4.2, as a single modality. Facilities which offer multiple or comprehensive surgical services, inclusive of termination of pregnancy, are designated as ambulatory surgery facilities. Whereas all of the rules at N.J.A.C. 8:43A–12 apply to ambulatory surgery facilities, only those rules at N.J.A.C. 8:43A–12 which are relevant to the levels of anesthesia used in a particular abortion facility shall apply to that facility.

"Advance directive" means a written statement of the patient's instructions and directions for health care in the event of future decision making incapacity. An advance directive may include a proxy directive or an instruction directive, or both.

"Affiliated community perinatal center" means a licensed hospital designated within a maternal and child health service region with which the birth center has a formal agreement for transfer and back-up services. This hospital must be designated as either a community perinatal center—intermediate or intensive or a regional perinatal center, in accordance with N.J.A.C. 8:33C.

"Ambulatory care facility" means a health care facility or a distinct part of a health care facility in which preventive, diagnostic, and treatment services are provided to persons who come to the facility to receive services and depart from the facility on the same day.

"Ambulatory surgery facility" means a surgical facility in which ambulatory surgical cases are performed and which is licensed as an ambulatory surgery facility, separate and apart from any other facility license. (The ambulatory surgery facility may be physically connected to another licensed facility, such as a hospital, but is corporately and administratively distinct.)

"Ambulatory surgical case" and "same day surgical case" are synonymous terms for a surgical procedure performed on a patient in a surgical facility generally requiring anesthesia, with a facility-based post surgery period of at least one hour, and generally without the requirement of an overnight stay.

"Available" means ready for immediate use (pertaining to equipment) or capable of being reached (pertaining to personnel), unless otherwise defined.

"Birth center" means a health care facility or a distinct part of a health care facility which provides routine prenatal and intrapartal care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2,499 grams and of 36 weeks gestational age and who require a stay of less than 24 hours after birth. "Routine intrapartal care" means labor and delivery services not requiring surgical intervention.

"Bylaws" means a set of rules adopted by the facility for governing its operation. A charter, articles of incorporation, or a statement of policies and objectives is an acceptable equivalent.

"Cardiac rehabilitation program" means a health care service in which an individualized program of physical exercise is prescribed for each cardiac patient.

"Chronic dialysis" means dialysis rendered to a patient with end stage renal disease in whom recovery of renal function is not expected.

"Cleaning" means the removal by scrubbing and washing, as with hot water, soap or detergent, and vacuuming of infectious agents and of organic matter from surfaces on which and in which infectious agents may find conditions for surviving or multiplying.

"Clinical note" means a written, signed, and dated notation made by a health care professional who renders a service to the patient. Clinical notes are written into the patient's medical record the day service is rendered.

"Clinical practitioner" means a physician, dentist, podiatrist, certified nurse midwife, physician assistant, or nurse practitioner.

"Commissioner" means the New Jersey State Commissioner of Health.

"Communicable disease" means an illness due to a specific infectious agent or its toxic products which occurs through transmission of that agent or its products from a reservoir to a susceptible host.

"Community perinatal center-birthing center" means a licensed birth center designated within a maternal and child health service region, in accordance with N.J.A.C. 8:33C.

"Comprehensive outpatient rehabilitation facility" means an ambulatory care facility which provides at least medical, physical therapy, and social or psychological services in a coordinated manner. The term applies to facilities which are certified or eligible for certification as comprehensive outpatient rehabilitation facilities in accordance with 42 CFR Part 485, Subpart B.

iii. In all areas of the facility where drugs are dispensed, administered, or stored, procedures for the intentional wasting of controlled drugs, including the disposition of partial doses, and for documentation, including the signature of a second person who shall witness the disposition;

8. The security of the keys or codes to locked drug storage areas, including specification of the personnel who may retain the keys or security codes. Only licensed nursing or medical personnel shall retain the keys or security codes to storage areas in which drugs subject to the Controlled Dangerous Substances Acts and amendments thereto are kept;

9. The control and limitation of use of drugs marked "sample";

10. The maintenance of records of prescribers' Controlled Dangerous Substance registration numbers and Drug Enforcement Administration registration numbers for New Jersey; and

11. Up-to-date pharmaceutical reference materials to be provided at locations specified in the facility's policies and procedures and made available to medical and nursing staff.

i. The telephone number of the designated Statewide or regional New Jersey Poison Information and Education System (1–800–962–1253) shall be provided at locations specified in the facility's policies and procedures.

ii. Current Federal and State drug law information shall be available to the pharmaceutical service.

iii. A list of abbreviations, metric apothecary conversion charts, and a list of chemical symbols, approved by the medical staff, shall be kept in areas where medications are prepared for administration.

8:43A–9.4 Administration of medications

(a) All medications administered shall be prescribed in writing. Each written order shall specify the name of the drug, dose, frequency, and route of administration and shall be signed and dated by the prescriber.

(b) Medications shall be dispensed only in accordance with prescriber orders and all Federal and State laws and rules. Medications shall be administered only in accordance with prescriber orders, medical staff policy, and all Federal and State laws and rules by licensed or authorized medical, dental, or nursing personnel.

(c) Medications shall not be removed from their original prescription containers until the time of drug administration.

(d) Each patient shall be identified prior to drug administration.

(e) Drugs dispensed for one patient shall not be administered to another patient.

(f) Drug allergies shall be documented in the patient's medical record and on its outside front cover. Other allergies shall be documented in the patient's medical record.

(g) Medication errors and adverse drug reactions shall be reported immediately to the nurse in charge and to the prescriber, and an entry shall be made in the patient's medical record. The incident shall be reported in accordance with procedures established by the facility. The incident shall be reported to the pharmacy, in accordance with policies and procedures approved by the patient care policy committee.

8:43A–9.5 Storage of drugs

(a) All drugs, except intravenous infusion solutions, shall be kept in locked storage areas. Drug storage and preparation areas shall be kept locked when not in use.

(b) All drugs shall be stored under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.

(c) Drugs for external use shall be kept separate from drugs for internal use.

(d) All drugs in Schedule II of the Controlled Dangerous Substances Acts and amendments thereto shall be stored in a separate, locked, permanently affixed compartment within the locked medication cabinet, medication room, refrigerator, or mobile medication cart.

(e) A declining inventory of all drugs in Schedules I through V of the Controlled Dangerous Substances Acts and amendments thereto shall be made at the termination of each shift and shall be retained wherever these drugs are maintained.

(f) Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source or exact identification (such as lot number), and outdated, recalled, or visibly deteriorated medications shall be returned to the institutional pharmacy for disposal. In the absence of an institutional pharmacy, such drugs shall be brought to a location specified in the facility's policies and procedures for disposal in accordance with Federal and State laws.

SUBCHAPTER 10. COUNSELING SERVICES

8:43A–10.1 Provision of counseling services

(a) The facility shall provide, directly or through written agreement or through a documented referral mechanism,

dietary counseling and social work services. All patients who have been identified as needing, or who have requested, other counseling services such as, but not limited to, genetic, psychological, and drug abuse counseling shall be referred to appropriate providers.

(b) The facility shall establish and implement written policies and procedures concerning the identification of the need for counseling services and referral to counseling services. The policies and procedures, which shall be reviewed at least annually, shall include, but not be limited to, policies and procedures for the following:

1. The provision, direction, and method to assure the quality of counseling services provided to patients;

2. The development and implementation of written objectives, standards of practice, and an organizational plan for counseling services;

3. Coordinating and integrating the counseling services with other patient care services in the facility and with services in the community to provide a continuum of care for the patient;

4. Staff orientation and staff education programs for the counseling staff; and

5. Entering in the patient's medical record:

i. The counseling service elements of the patient plan of care; and

ii. Clinical notes.

8:43A–10.2 Provision of social work services

Social work services which fall within the scope of practice defined by the Social Workers' Licensing Act of 1991 (N.J.S.A. 45:15BB–1 et seq.) and the New Jersey State Board of Social Work Examiners shall be provided by a social worker.

8:43A–10.3 Provision of dietary counseling

Dietary counseling which falls outside of the scope of practice defined by the State of New Jersey Nursing Practice Act and the New Jersey State Board of Nursing shall be provided by a dietitian.

SUBCHAPTER 11. LABORATORY AND RADIOLOGICAL SERVICES

8:43A–11.1 Provision of laboratory and radiological services

(a) The facility shall provide laboratory and radiological services directly or through written agreement.

(b) Laboratory services shall be provided only by facilities which are licensed or approved by the Department, in accordance with N.J.A.C. 8:44 and 8:45.

(c) Radiological services shall be provided only by facilities which are registered by the New Jersey State Department of Environmental Protection, Bureau of Radiological Health, in accordance with N.J.A.C. 7:28.

(d) The facility shall establish and implement policies and procedures for obtaining, identifying, storing, and transporting laboratory specimens.

SUBCHAPTER 12. SURGICAL AND ANESTHESIA SERVICES

8:43A–12.1 Services

(a) If the facility provides surgical services to patients, the surgical and anesthesia services provided shall be limited to those procedures approved by the governing authority and the medical staff.

(b) Surgical procedures requiring the patient to remain in the facility for more than 24 hours shall not be performed in the facility.

8:43A–12.2 Definitions

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

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

"Anesthetizing location" means any location in a health care facility where anesthetic agents are administered.

"Conduction anesthesia" means the administration of anesthetic agents to interrupt nerve impulses without loss of consciousness. Major conduction blocks include regional nerve blocks (epidural, caudal, and spinal anesthesia). Minor conduction blocks include local infiltration, local nerve blocks, and nerve blocks by direct pressure and refrigeration.

"Conscious sedation" means the administration of drugs to obtund, or dull or reduce the intensity of, pain and awareness without the loss of defensive reflexes.

"Credentialed" means granted the privilege by the ambulatory care facility to provide specified anesthesia services, such as administration or supervision of one or more types of anesthetic agents or procedures.

"Deep sedation" means the administration of drugs which results in some loss of defensive reflexes; the patient, however, remains arousable by strong stimulation.

"Defensive reflexes" means the ability of an individual to counteract noxious events, especially to defend the breathing passages against foreign material.

"General anesthesia" means the administration of drugs which causes loss of consciousness, that is, complete unawareness of routine surroundings. During general anesthesia the patient is unable to make meaningful responses to even the strongest stimulation.

"Local anesthetic" 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 a local anesthetic to stop a painful sensation in a severely circumscribed area of the body (local infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration.

"Monitoring" means the observation of a patient using instruments to measure, display, and/or record (continuously or intermittently) the values of certain physiologic variables such as pulse, blood pressure, oxygen saturation, and respiration.

"Operating room" means a unit for the performance of surgery.

"Practitioner" means a physician, a dentist, or a podiatrist.

"Regional anesthesia" means a major conduction block such as epidural, caudal, and spinal anesthesia.

"Special procedure" means patient care which requires entering the body with instruments in a potentially painful manner. Examples are: endoscopy (diagnostic and surgical), oral surgery, radiologic procedures, or emergency procedures.

"Special procedure room" means the specially equipped facility location in which special procedures are performed.

"Supervision" means responsibility by a physician who is credentialed in accordance with medical staff bylaws, and who is immediately available for overseeing the administration and monitoring of anesthesia by anesthesia personnel. "Immediately available" means that the supervising physician is present in the facility and is available to respond and proceed immediately to the anesthetizing location.

8:43A–12.3 Surgical and anesthesia staff; qualifications

(a) Surgical procedures shall be performed only by practitioners who are licensed to practice in New Jersey and who have been granted privileges to perform those procedures by the governing body of the facility, upon the recommendation of the medical staff, after medical review of each practitioner's documented education, training, experience, and current competence.

(b) A physician and a registered professional nurse, at least one of whom is certified in advanced cardiac life support by the American Heart Association, shall be present during all surgical procedures and shall be present in the facility as long as any patient remains in the facility.

(c) There shall be a physician director of anesthesia services who 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. The medical director of the facility may serve as physician director of anesthesia services, if the medical director possesses the qualifications of a physician director of anesthesia services as specified in this subsection.

1. Facilities in which conscious sedation only is administered may, in lieu of appointing a director of anesthesia services as specified in (a) above, ensure that each of the physicians who administer, supervise, or monitor the administration of conscious sedation in the facility is credentialed by an acute care hospital, licensed in New Jersey in accordance with N.J.A.C. 8:43G, to administer, supervise, and monitor the administration of conscious sedation.

(d) The physician director of anesthesia services shall participate in the credentialing process and delineation of privileges of all personnel who administer anesthetic agents.

(e) Anesthetic agents administered with the purpose of creating conscious sedation, deep sedation, conduction anesthesia, or general anesthesia shall be administered in any location in the facility only in accordance with medical staff policies and procedures.

(f) All anesthetic agents, except those utilized for conscious sedation or as minor conduction blocks, shall be administered and monitored only by the following:

1. An anesthesiologist;

2. Under the supervision of an anesthesiologist:

i. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification; or

ii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally

approved graduate training program leading to a recognized specialty;

3. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise the administration of anesthesia:

i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the AANA; or

4. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.

(g) The administration and monitoring of any anesthesia, except those agents utilized for conscious sedation or minor conduction blocks, shall be provided by an individual who is continuously present and separate from the individual who is performing the procedure.

(h) The supervision of any anesthesia, except those agents utilized for conscious sedation or minor conduction blocks, shall be provided by a physician who is credentialed in accordance with medical staff bylaws and who is immediately available. The supervising physician may concurrently be responsible for patient care if he or she is available to attend to supervisory duties without jeopardizing the life or safety of patients under his or her care. While supervising anesthesia personnel, the supervising physician shall not perform surgery, except minor surgery as defined by medical staff policy, or administer anesthesia to patients under his or her direct care.

(i) Anesthetic agents used for conscious sedation shall be administered only by the following:

1. A physician who has been credentialed in accordance with medical staff bylaws to administer anesthetic agents used for conscious sedation;

2. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise anesthetic agents used for conscious sedation and who is immediately available:

i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA);

ii. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the AANA, provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification; or

iii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or

3. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.

(j) The monitoring of patients who have been administered an anesthetic agent for the purpose of creating conscious sedation shall be provided by an individual who is continuously present for the primary purpose of anesthesia monitoring, who is separate from the individual performing the procedure, and who is one of the following:

1. A physician who has been credentialed in accordance with medical staff bylaws to administer anesthetic agents used for conscious sedation;

2. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise anesthetic agents used for conscious sedation and who is immediately available:

i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA);

ii. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the AANA, provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification;

iii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or

iv. A registered professional nurse who is certified in basic cardiac life support and who has training and experience in the use of monitoring devices; or

3. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.

(k) Minor conduction blocks shall be administered only by the following:

1. A physician who has been credentialed in accordance with medical staff bylaws to administer minor conduction blocks;

2. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise minor conduction blocks and who is immediately available:

i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the AANA;

ii. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the AANA, provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification;

iii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or

iv. A certified nurse midwife, a physician assistant, or a nurse practitioner, as permitted by the scope of practice rules of the New Jersey State Board of Medical Examiners and the New Jersey State Board of Nursing, as applicable; or

3. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.

(*l*) Minor conduction blocks shall be monitored continuously by licensed medical or licensed nursing personnel.

(m) Provision shall be made for remote monitoring of the patient if radiation or another direct hazard necessitates the removal of personnel.

(n) A facility providing surgical services shall have a registered professional nurse other than the director of nursing services to serve as circulating nurse. There shall also be at least one registered professional nurse other than the director of nursing services present whenever a patient is in the postanesthesia care unit. (One person may satisfy both of these requirements if there is no patient in the operating room or no patient in the postanesthesia care unit.)

8:43A–12.4 Policies and procedures

(a) The facility shall develop and implement written bylaws, rules, regulations, policies, and procedures for surgical and anesthesia services, in accordance with the governing authority and medical staff bylaws. The policies and procedures shall be reviewed annually and revised as needed, and shall include at least the following:

1. Delineation of the surgical and anesthesia services which may be performed in the facility;

2. Delineation of the responsibilities of medical staff members in providing care to patients;

3. Designation of a time frame and of persons responsible for completing a medical history, physical examination, and laboratory tests prior to surgery;

4. Policies and procedures regarding preanesthesia evaluation, patient preparation, and intraoperative management;

5. Policies and procedures to ensure that every patient is examined by a practitioner immediately prior to surgery;

6. Policies and procedures for use of analgesia and anesthesia, including types which may be used for each procedure, safety regulations, and responsibilities and qualifications of persons who administer anesthesia and monitor patients;

7. Policies and procedures for the preoperative and postoperative recording of vital signs (blood pressure, temperature, respiration rate, and pulse);

8. Policies and procedures for reporting of morbidity and mortality;

9. Policies and procedures for monitoring of patients in any special procedure room or other location where patients receive anesthesia;

10. Policies and procedures for postoperative observation and care required for each type of procedure;

11. Methods to ensure that gross and microscopic tissue removed surgically or by any other procedure, including termination of pregnancy in accordance with the regulations of the New Jersey State Board of Medical Examiners, N.J.A.C. 13:35–4.2, is examined by a pathologist and a report of the findings is documented in the patient's medical record;

i. The facility shall ensure that the tissue is disposed of in accordance with N.J.A.C. 8:43A–14.7 of this chapter whether it is examined on the facility's premises or off the facility's premises;

12. Specification of the duration of time the patient shall remain in the facility after surgery;

13. Requirements for written documentation of surgical procedures performed, including at least a description of the findings, procedures used, specimens removed, patient's condition, any unusual events occurring during the procedure, postoperative diagnosis, and names of the surgeon and assistants. This operative note shall be written or dictated immediately following the procedure by the person performing the surgery and incorporated into the patient's medical record;

14. Policies and procedures for the provision of written instructions to the patient (multilingual, if indicated) on pre-and postsurgical care, including, but not limited to, restrictions on food and beverages before surgery and procedures for obtaining help in the event of surgical wound infection or other postoperative problems;

15. Policies and procedures regarding infection prevention and control, including, but not limited to, the following:

i. Designation of a person with training or experience in surveillance, prevention, and control of nosocomial infection who shall be responsible for the direction, provision, and quality of infection prevention and control services;

ii. Use of aseptic technique and scrub procedures;

iii. Gowning and operating room attire, including changing of masks between procedures;

iv. Traffic control;

v. Cleaning of the operating room after each procedure; and

vi. Care of operating room equipment and anesthesia equipment; and

16. Procedures for a systematic review and evaluation of patient care and surgical and anesthesia practices and techniques, as part of the quality assurance program of the facility.

i. Quality assurance shall include morbidity and mortality conferences.

ii. Quality assurance activities shall include at least the monitoring of outcomes for patients receiving anesthetic agents and postdischarge follow-up of surgical procedures.

iii. The facility shall notify the Division of Health Facilities Evaluation and Licensing, New Jersey State Department of Health, by telephone at (609) 588–7727 or (800) 792–9770 within 24 hours, and in writing within 30 days, of all deaths in anesthetizing locations and unexpected intraoperative or postoperative events or outcomes related to anesthesia. The written report shall include a summary of the incident and the patient's risk status or American Society of Anesthesiology (ASA) Physical Status classification. Records of such reports and telephone calls shall be made available only to Department of Health personnel for official purposes and, for each report, to the specific facility to which the report pertains.

8:43A–12.5 Records

(a) The facility shall maintain a record of all surgical procedures performed which shall include the type of procedure performed, operative diagnosis, type of anesthesia used, personnel participating, postoperative diagnosis, and any unusual or untoward occurrence.

(b) A preanesthesia note, reflecting evaluation of the patient and of the patient record prior to administration of anesthesia, shall be made or reviewed by the physician administering or supervising the administration of anesthesia and entered into the medical record of each patient receiving anesthesia at any anesthetizing location.

(c) A record of anesthesia that conforms with policies and procedures developed by the medical staff shall be made for each patient receiving sedation or anesthesia at any anesthetizing location.

(d) Postanesthesia notes shall be entered into the patient's medical record early in the postoperative period by a member of the facility's anesthesia team and after the patient's discharge from the postanesthesia care unit by a member of the postanesthesia care unit staff.

(e) The patient's medical record shall include a pathologist's report of gross and microscopic tissue surgically removed.

8:43A–12.6 Surgical service emergency equipment

(a) Emergency equipment available to the operating room in a surgical service shall include at least the following:

1. Emergency call system;
2. Oxygen;
3. Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator;
4. Cardiac defibrillator;
5. Cardiac monitoring equipment;
6. Tracheostomy set;
7. Laryngoscopes and endotracheal tubes;
8. Suction equipment with catheter tip; and
9. Emergency drugs and supplies specified by the medical staff in the facility's policies and procedures.

8:43A–12.7 Anesthesia supplies and equipment; safety systems

(a) Diameter index safety systems or equivalent systems shall be used on all large cylinders of medical gases and wall and ceiling outlets of medical gases.

(b) Pin index safety systems with a single washer shall be used on all small cylinders to prevent interchangeability of medical gas cylinders.

(c) All medical gas hoses and adapters shall be color-coded.

(d) An oxygen failure-protection device ("fail-safe" system) shall be used on all anesthesia machines to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced.

(e) A vaporizer exclusion ("interlock") system shall be used to assure that only one vaporizer, and therefore only a single agent, can be actuated on any anesthesia machine at one time.

(f) To prevent delivery of excess anesthesia during an oxygen flush, no vaporizer shall be placed in the circuit downstream of the oxygen flush valve.

(g) All anesthesia vaporizers shall be pressure-compensated in order to administer a constant non-pulsatile output.

(h) Accurate flow meters and controllers shall be used to prevent the delivery to a patient of an inadequate concentration of oxygen relative to the amount of nitrous oxide or other medical gas.

(i) Alarm systems shall be in place for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia.

(j) There shall be a written policy to ensure that surgery does not proceed when there are disabled alarms, depleted batteries and inactive sensors in oxygen monitors, improperly positioned breathing-circuit sensors, or other insufficiencies.

8:43A–12.8 Anesthesia supplies and equipment; maintenance and inspections

(a) A record shall be maintained of all service and maintenance performed on all anesthesia machines, ventilators, and vaporizers. The record shall include machine identification; the name of the servicing agent; the work performed; and the date of the work. This maintenance shall conform with maintenance requirements established by the machine manufacturer. Credentials of each servicing agent shall be approved by the machine manufacturer or shall be determined by the physician director of anesthesia services to be equivalent to the credentials of manufacturers' servicing agents.

(b) All anesthesia equipment shall be inspected fully at the beginning of each day of use. A record of each such inspection shall be maintained for each machine. The inspection shall conform with a checklist that is supplied by the manufacturer of the machine, issued by the Federal Food and Drug Administration, or, alternatively, developed by the facility's anesthesia services and approved by the physician director of anesthesia services.

(c) All anesthesia equipment shall be inspected before each use. A record of each inspection shall be included in the patient's anesthesia record. Each record may consist of a single phrase or check mark in a box on a form.

8:43A–12.9 Anesthesia supplies and equipment; patient monitoring

(a) An in-circuit oxygen analyzer shall monitor the oxygen concentration within the breathing circuit, displaying the percent oxygen of the total mixture, for all patients receiving general anesthesia.

(b) A respirometer (volumeter) measuring exhaled tidal volume shall be used whenever the breathing circuit of a patient under general anesthesia allows.

(c) The body temperature of each patient under general or regional anesthesia shall be continuously monitored.

(d) Pulse oximetry shall be performed continuously during administration of general anesthesia, regional anesthesia, or conscious sedation, at all anesthetizing locations, unless such monitoring is not clinically feasible for the patient. 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.

(e) End-tidal carbon dioxide monitoring shall be performed continuously during administration of all general anesthesia to intubated patients, unless such monitoring is not clinically feasible for the patient.

(f) An electrocardiogram monitor shall be used continuously on all patients receiving general anesthesia, regional anesthesia, or conscious sedation at any anesthetizing location.

(g) Blood pressure, pulse rate, and respirations shall be determined and charted at least every five minutes for all patients receiving anesthesia at any anesthetizing location.

(h) A precordial stethoscope or esophageal stethoscope shall be used when indicated on each patient receiving anesthesia. If necessary, the stethoscope may be positioned on the posterior chest wall or tracheal area.

(i) A peripheral nerve stimulator shall be available to any anesthetizing location in which patients receive general or regional anesthesia to monitor the patient's extent of muscle paralysis from muscle relaxants. Another peripheral nerve stimulator shall be available within the postanesthesia care unit.

8:43A–12.10 Anesthesia staff education and training

Anesthesia staff education programs and training sessions shall include, but not be limited to, patient safety and the inspection and use of equipment.

8:43A–12.11 Postanesthesia care policies and procedures

(a) Facilities providing anesthesia services shall have a postanesthesia care unit.

(b) The postanesthesia care unit shall have written policies and procedures which are reviewed annually, revised as needed, and implemented. These shall include at least:

1. Criteria for admission to and discharge from the unit;

2. Delineation of the primary medical responsibility for postanesthesia and postsurgical care of each patient in the unit, including authority to discharge;

3. Policies and procedures regarding monitoring of patients in the postanesthesia care unit, including availability of monitoring equipment;

4. Protocol of care for all patients;

5. Protocol for patient emergencies;

6. Policies and procedures regarding orders for intravenous administration of medications;

7. Requirements for documentation of patient status; and

8. A requirement that patients who receive anesthesia, excluding minor conduction blocks, not drive themselves home after discharge and that they be accompanied home by another person who accepts responsibility for the patient. If the patient fails to comply with the requirement, the circumstances shall be documented in the patient's medical record.

8:43A–12.12 Postanesthesia care staff qualifications

(a) There shall be a physician director with overall responsibility for postanesthesia care. The physician director of anesthesia services may serve as physician director of postanesthesia care.

(b) There shall be a registered professional nurse with administrative responsibility for nursing care provided in the postanesthesia care unit.

(c) All registered professional nurses assigned to the postanesthesia care unit shall be trained in postanesthesia care, including at least:

1. Management of airway and ventilatory function;

2. Monitoring of cardiac function, arrhythmia recognition, and treatment of life-threatening emergencies;

3. Management of the patient during altered states of consciousness;

4. Management of monitoring and respiratory equipment;

5. Management of fluid lines, tubes, drains, and catheters;

6. Cardiopulmonary resuscitation;

7. Administration of drugs and identification of drug-related problems; and

8. Recognition of the actions and interactions of anesthetic techniques.

(d) All registered professional nurses in the postanesthesia care unit shall have training in basic cardiac life support and in critical care.

8:43A–12.13 Postanesthesia care staff time and availability

There shall be at least one registered professional nurse present whenever a patient is in the postanesthesia care unit, and a second health care staff member shall be immediately available. Additional nursing staff shall be assigned on the basis of the volume and case mix of patients in the unit.

8:43A–12.14 Postanesthesia care patient services

(a) The patient shall be accompanied to the postanesthesia care unit by two individuals, one of whom, stationed at the patient's head, shall be a member of the anesthesia team.

1. If a patient who has received conscious sedation or a minor conduction block is able to walk to the postanesthesia care unit, the patient shall be accompanied by at least one individual, who shall be a member of the anesthesia team.

(b) An oral report on the patient's condition shall be given to postanesthesia care unit nursing staff by a member of the anesthesia team when the patient is admitted to the postanesthesia care unit.

(c) A member of the anesthesia team shall stay with the patient in the postanesthesia care unit at least until the patient's vital signs, including blood pressure, pulse, and respiration, are recorded.

(d) The postanesthesia care unit shall continually evaluate the condition of each patient and maintain an accurate written report of his or her vital signs, with an objective scoring system used to track the patient's recovery from anesthesia from the time of admission to the unit until discharge from the postanesthesia care unit.

(e) Electrocardiographic monitoring shall be conducted for each patient who has received general anesthesia or regional anesthesia, unless such monitoring is not clinically feasible for the patient.

(f) Each patient who has received general anesthesia or regional anesthesia shall be monitored by pulse oximetry, unless such monitoring is not clinically feasible for the patient.

(g) The postanesthesia care unit shall have immediate access to end-tidal carbon dioxide monitoring, if general anesthesia is administered to intubated patients in the facility.

(h) The medical record maintained for each patient in the postanesthesia care unit shall include at least such preoperative data as allergies, physical and mental impairments, prostheses, electrocardiogram, vital signs, radiologic findings, laboratory values, drug use, and mobility limitations.

(i) The medical record maintained for each patient in the postanesthesia care unit shall include at least such postoperative data as the patient's general condition, respiration, consciousness, circulation, special problems or precautions, summary of fluids received during surgery, and oxygen saturation.

(j) Patients shall be discharged from the postanesthesia care unit using discharge criteria, including authority to discharge, which have been developed through the postanesthesia policies and procedures specified at N.J.A.C. 8:43A–12.11(b).

8:43A–12.15 Postanesthesia care units and equipment

(a) Postanesthesia care units shall be adjacent to or within the operating suite.

(b) The postanesthesia care unit shall be maintained as a closed unit. Access to the restricted zone of the postanesthesia care unit shall be through or past a control center.

(c) All staff in the postanesthesia care unit shall be attired in scrub attire. Any other individuals who are permitted limited access shall wear scrub attire, cover gowns, or jumpsuits.

(d) Equipment and services available in the postanesthesia care unit shall include at least emergency equipment and drugs, pulse oximetry, electrocardiographic monitoring, body temperature monitoring, equipment necessary for intubation and extubation, respirometer, various means of oxygen delivery, constant and intermittent suction, blood pressure monitoring, adjustable lighting, peripheral nerve stimulator, equipment which ensures protection of the patient's privacy, and immediate access to a ventilator and to end-tidal carbon dioxide monitoring in accordance with N.J.A.C. 8:43A-12.14(g).

1. If neither general anesthesia nor regional anesthesia is administered in the facility, then the requirements for pulse oximetry, electrocardiographic monitoring, and a peripheral nerve stimulator in (d) shall not apply to the postanesthesia care unit.

(e) If the facility provides a second stage recovery area in addition to a postanesthesia care unit, the requirements of (a) through (d) above shall not apply to the second stage recovery area.

8:43A–12.16 Designation of consultant pharmacist

If an ambulatory surgical facility does not have an institutional pharmacy, the facility shall designate a consultant pharmacist who shall review all facility policies and procedures concerning the administration, control, and storage of medications at least semiannually. The consultant pharmacist shall not be affiliated with the pharmacy which provides pharmaceutical services for the facility.

8:43A–12.17 Physical plant

(a) New ambulatory surgical facilities shall comply with Chapter 9, Sections 9.1 and 9.2, and with Chapter 9, Section 9.5, Outpatient Surgical Facility, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992–1993 edition, as amended, incorporated herein by reference. (American Institute of Architects–Press, 1735 New York Ave., NW, Washington, D.C. 20006)

(b) When the ambulatory surgical facility is part of an acute care hospital's surgical suite, support services may be shared to avoid duplication. When inpatients and outpatients are served in the same suite, the functional program shall describe in detail scheduling and techniques used to separate inpatients from outpatients.

8:43A–12.18 Exceptions for local anesthesia

Facilities in which local anesthesia or minor conduction blocks only are administered are exempt from complying with the requirements for anesthesia services in this subchapter, except that such facilities shall comply with the following: N.J.A.C. 8:43A–12.1, 12.3(e), 12.3(k), 12.3(*l*), 12.4(a)1, 12.4(a)2, 12.4(a)4, and 12.4(a)6. The facility shall also comply with N.J.A.C. 8:43A–12.9(g), except that the frequency of determining and charting blood pressure, pulse rate, and respirations may be determined by the facility and specified in the policies and procedures of the facility.

SUBCHAPTER 13. MEDICAL RECORDS

8:43A–13.1 Maintenance of medical records

(a) A current, complete medical record shall be established and maintained for each patient and shall contain documentation of all services provided.

(b) Written objectives, policies and procedures, an organizational plan, and a quality assurance program for medical record services shall be developed and implemented. All medical records policies and procedures shall be reviewed at least annually.

(c) Original medical records or components of medical records shall not leave facility premises unless they are under court order or subpoena or removed in order to safeguard the record in the case of a physical plant emergency or natural disaster. Off-site storage of records may be used only if the Department is given prior notice, including the details of the storage arrangement, and only if such storage arrangements will ensure retrieval and delivery of the patient's medical record to the facility within one business day on a seven day per week, 24 hour per day, basis and immediate availability of medical record information through telephone and facsimile communications systems.

(d) A record system shall be maintained in which the patient's complete medical record is filed as one unit, and there shall be a system of access and identification for the medical records of all patients.

8:43A–13.2 Assignment of responsibility

An employee shall be designated to act as coordinator of medical record services. The facility shall designate an employee to act in the absence of the coordinator to ensure staff access to the medical record at all times during the hours of operation.

8:43A–13.3 Contents of medical records

(a) The complete medical record shall include, but not be limited to, the following:

1. Patient identification data, including name, date of admission, address, date of birth, race, religion (optional), sex, and the name, address, and telephone number of the person(s) to be notified in an emergency;

2. The patient's complaint or purpose of the visit;

3. The diagnosis or medical impressions;

4. Orders for laboratory, radiological, diagnostic, and/or screening tests and their results;

5. All orders for treatment, medication, and diets, signed by the prescriber;

6. Documentation of the medical history and physical examination, if performed, signed and dated by the examiner;

7. Patient assessments developed by each service providing care to the patient;

8. A patient plan of care, in accordance with the facility's policies and procedures;

9. Clinical notes, which shall be entered on the day service is rendered;

10. A medication sheet indicating at least the name, date, dosage, and duration of all medications prescribed;

11. A record of medications administered, including the name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature of the person who administered the drug;

12. Documentation of drug allergies in the medical record and on its outside front cover and documentation of other allergies in the medical record;

13. An immunization record, in accordance with the facility's policies and procedures;

14. A record of referrals to or from other health care providers;

15. Documentation of any consultations ordered or provided;

16. Documentation that informed consent was obtained for any procedure or treatment provided which is specified in the facility's policies and procedures as requiring informed consent;

17. Documentation regarding an advance directive, if applicable;

18. The patient's signed acknowledgement that the patient has been informed of patient rights, either verbally or through written copy, and has been offered a copy;

19. Instructions given to the patient and/or family for follow-up care;

20. A record of any treatment, drug, or service offered by personnel of the facility and refused by the patient;

21. The discharge plan, where applicable, and a discharge summary sheet containing the patient's name, address, dates of admission and discharge, and a summary of the treatment and medication rendered during the patient's stay; and

22. Any authorizations granted by the patient for release of the patient's medical record.

8:43A–13.4 Requirements for entries

(a) All orders for patient care shall be prescribed in writing and signed and dated by the prescriber, in accordance with the laws of the State of New Jersey. All orders, including verbal orders, shall be verified or countersigned in writing within seven days.

(b) All entries in the medical record shall be typewritten or written legibly in ink, dated, and signed by the person entering them, or, if a computerized medical records system is used, authenticated.

1. If computer-generated orders with a physician's electronic signature are used, the facility shall develop a procedure to assure the confidentiality of each electronic signature and to prohibit the improper or unauthorized use of any computer-generated signature.

2. If a facsimile communications system (FAX) is used, entries into the medical record shall be in accordance with the following procedures:

i. The physician shall sign the original order, history and/or examination at an off-site location;

ii. The original shall be transmitted by FAX system to the facility for inclusion into the medical record;

iii. The physician shall submit the original for inclusion into the medical record within seven days, unless a plain-paper laser facsimile process was used; and

iv. The copy transmitted by FAX system shall be replaced by the original, unless a plain-paper laser facsimile process was used.