

CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSURE OF AMBULATORY CARE SERVICES

Authority

N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5.

Source and Effective Date

R.1998 d.535, effective November 16, 1998.
See: 30 N.J.R. 2558(a), 30 N.J.R. 4070(c).

Executive Order No. 66(1978) Expiration Date

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

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Chapter 43A, Ambulatory Care Facilities, was repealed and Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was adopted as new rules by R.1985 d.438, effective September 3, 1985.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 (1988), 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was readopted as R.1993 d.443, effective August 16, 1993, and Subchapters 1 through 11 and 13 through 19 were repealed and new Subchapters 1 through 11 and 13 through 29 were adopted by R.1993 d.443, effective September 7, 1993.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: Source and Effective Date.

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

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

- 8:43A-1.1 Scope
- 8:43A-1.2 Purpose
- 8:43A-1.3 Definitions

- 8:43A-1.4 Qualifications of the administrator of the ambulatory care facility
- 8:43A-1.5 Qualifications of anesthesiologists
- 8:43A-1.6 Qualifications of certified nurse midwife
- 8:43A-1.7 Qualifications of certified registered nurse anesthetists (CRNA)
- 8:43A-1.8 Qualifications of dentists
- 8:43A-1.9 Qualifications of dietitians
- 8:43A-1.10 Qualifications of the director of nursing services
- 8:43A-1.11 Qualifications of drug counselors
- 8:43A-1.12 Qualifications of family practice physicians
- 8:43A-1.13 Qualifications of licensed practical nurses
- 8:43A-1.14 Qualifications of the medical director
- 8:43A-1.15 Qualifications of nephrologists
- 8:43A-1.16 Qualifications of nurse practitioners
- 8:43A-1.17 Qualifications of obstetrician-gynecologists
- 8:43A-1.18 Qualifications of pediatricians
- 8:43A-1.19 Qualifications of pharmacists
- 8:43A-1.20 Qualifications of physician assistants
- 8:43A-1.21 Qualifications of physicians
- 8:43A-1.22 Qualifications of podiatrists
- 8:43A-1.23 Qualifications of radiation physicists/health physicists
- 8:43A-1.24 Qualifications of radiologic technologists
- 8:43A-1.25 Qualifications of radiologists
- 8:43A-1.26 Qualifications of registered professional nurses
- 8:43A-1.27 Qualifications of social workers
- 8:43A-1.28 Qualifications of urologists

SUBCHAPTER 2. LICENSURE PROCEDURES

- 8:43A-2.1 Certificate of need
- 8:43A-2.2 Application for licensure
- 8:43A-2.3 Types of services requiring a license
- 8:43A-2.4 Newly constructed or expanded facilities
- 8:43A-2.5 Surveys and temporary license
- 8:43A-2.6 Full license
- 8:43A-2.7 Conditional license
- 8:43A-2.8 Surrender of license
- 8:43A-2.9 Waiver
- 8:43A-2.10 Action against a license
- 8:43A-2.11 Hearings

SUBCHAPTER 3. GENERAL REQUIREMENTS

- 8:43A-3.1 Provision of services
- 8:43A-3.2 Compliance with laws and rules
- 8:43A-3.3 Ownership
- 8:43A-3.4 Submission of documents and data
- 8:43A-3.5 Personnel
- 8:43A-3.6 Policy and procedure manual
- 8:43A-3.7 Employee health
- 8:43A-3.8 Reportable events
- 8:43A-3.9 Notices
- 8:43A-3.10 Information reportable to State Board of Medical Examiners
- 8:43A-3.11 Reporting to professional licensing boards
- 8:43A-3.12 Reporting requirements for ambulatory surgery facilities

SUBCHAPTER 4. GOVERNING AUTHORITY

- 8:43A-4.1 Responsibility of the governing authority

SUBCHAPTER 5. ADMINISTRATION

- 8:43A-5.1 Appointment of administrator
- 8:43A-5.2 Administrator's responsibilities

SUBCHAPTER 6. PATIENT CARE POLICIES AND SERVICES

- 8:43A-6.1 Establishment and implementation of policies and procedures
- 8:43A-6.2 Patient care policy committee

- 8:43A-6.3 Policies and procedures
- 8:43A-6.4 Medical history and physical examination
- 8:43A-6.5 Instructions and information for patients
- 8:43A-6.6 Communication assistance
- 8:43A-6.7 Suitability of equipment and supplies
- 8:43A-6.8 Financial arrangements
- 8:43A-6.9 Smoking in facility
- 8:43A-6.10 Calibration of instruments
- 8:43A-6.11 Acupuncture services

SUBCHAPTER 7. MEDICAL SERVICES

- 8:43A-7.1 Provision of medical services
- 8:43A-7.2 Designation of medical director
- 8:43A-7.3 Medical director's responsibilities
- 8:43A-7.4 Medical policies and medical staff bylaws

SUBCHAPTER 8. NURSING SERVICES

- 8:43A-8.1 Provision of nursing services
- 8:43A-8.2 Designation of director of nursing services
- 8:43A-8.3 Responsibilities of director of nursing services
- 8:43A-8.4 Responsibilities of licensed nursing personnel
- 8:43A-8.5 Nursing portion of the medical record

SUBCHAPTER 9. PHARMACEUTICAL SERVICES

- 8:43A-9.1 Provision of pharmaceutical services through an institutional pharmacy
- 8:43A-9.2 Scope
- 8:43A-9.3 Policies and procedures
- 8:43A-9.4 Administration of medications
- 8:43A-9.5 Storage of drugs

SUBCHAPTER 10. COUNSELING SERVICES

- 8:43A-10.1 Provision of counseling services
- 8:43A-10.2 Provision of social work services
- 8:43A-10.3 Provision of dietary counseling

SUBCHAPTER 11. LABORATORY AND RADIOLOGICAL SERVICES

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

SUBCHAPTER 12. SURGICAL AND ANESTHESIA SERVICES

- 8:43A-12.1 Services
- 8:43A-12.2 Definitions
- 8:43A-12.3 Surgical and anesthesia staff; qualifications
- 8:43A-12.4 Policies and procedures
- 8:43A-12.5 Records
- 8:43A-12.6 Surgical service emergency equipment
- 8:43A-12.7 Anesthesia supplies and equipment; safety systems
- 8:43A-12.8 Anesthesia supplies and equipment; maintenance and inspections
- 8:43A-12.9 Anesthesia supplies and equipment; patient monitoring
- 8:43A-12.10 Anesthesia staff education and training
- 8:43A-12.11 Postanesthesia care policies and procedures
- 8:43A-12.12 Postanesthesia care staff qualifications
- 8:43A-12.13 Postanesthesia care staff time and availability
- 8:43A-12.14 Postanesthesia care patient services
- 8:43A-12.15 Postanesthesia care units and equipment
- 8:43A-12.16 Designation of consultant pharmacist
- 8:43A-12.17 Physical plant
- 8:43A-12.18 Exceptions for local anesthesia

SUBCHAPTER 13. MEDICAL RECORDS

- 8:43A-13.1 Maintenance of medical records
- 8:43A-13.2 Assignment of responsibility
- 8:43A-13.3 Contents of medical records
- 8:43A-13.4 Requirements for entries
- 8:43A-13.5 Medical records policies and procedures
- 8:43A-13.6 Preservation, storage, and retrieval of medical records

SUBCHAPTER 14. INFECTION PREVENTION AND CONTROL SERVICES

- 8:43A-14.1 Administrator's responsibilities
- 8:43A-14.2 Infection control policies and procedures
- 8:43A-14.3 Infection prevention measures
- 8:43A-14.4 Use and sterilization of patient care items
- 8:43A-14.5 Care and use of sterilizers
- 8:43A-14.6 Regulated medical waste
- 8:43A-14.7 Disposition of tissue

SUBCHAPTER 15. EMERGENCY SERVICES AND DISASTER PLANS

- 8:43A-15.1 Disaster planning
- 8:43A-15.2 Drills, tests, and inspections
- 8:43A-15.3 Emergency medical services

SUBCHAPTER 16. PATIENT RIGHTS

- 8:43A-16.1 Policies and procedures
- 8:43A-16.2 Rights of each patient
- 8:43A-16.3 Notice

SUBCHAPTER 17. HOUSEKEEPING, SANITATION AND SAFETY

- 8:43A-17.1 Provision of services
- 8:43A-17.2 Housekeeping
- 8:43A-17.3 Patient care environment
- 8:43A-17.4 Waste removal
- 8:43A-17.5 Water supply
- 8:43A-17.6 Laundry services

SUBCHAPTER 18. QUALITY ASSURANCE PROGRAM

- 8:43A-18.1 Quality assurance plan
- 8:43A-18.2 Quality assurance activities

SUBCHAPTER 19. PHYSICAL PLANT AND FUNCTIONAL REQUIREMENTS

- 8:43A-19.1 Physical plant general compliance for new construction or alteration
- 8:43A-19.2 Physical plant general compliance for construction or alteration completed prior to the effective date of this chapter
- 8:43A-19.3 Plan review fees
- 8:43A-19.4 Alterations and repairs
- 8:43A-19.5 Provision for the handicapped
- 8:43A-19.6 Common elements for ambulatory health care facilities
- 8:43A-19.7 Small ambulatory care facilities

SUBCHAPTER 20. FAMILY PRACTICE SERVICES

- 8:43A-20.1 Additional requirements
- 8:43A-20.2 Medical staff to be provided

SUBCHAPTER 21. FAMILY PLANNING, PRENATAL, POSTPARTUM, AND GYNECOLOGICAL SERVICES

- 8:43A-21.1 Additional requirements and exceptions
- 8:43A-21.2 Medical staff to be provided
- 8:43A-21.3 Medical history
- 8:43A-21.4 Medical records
- 8:43A-21.5 (Reserved)

SUBCHAPTER 22. PEDIATRIC SERVICES

- 8:43A-22.1 Additional requirements
- 8:43A-22.2 Medical staff to be provided
- 8:43A-22.3 Medical records

SUBCHAPTER 23. PRIMARY CARE

- 8:43A-23.1 Additional requirements

- 8:43A-23.2 Infection prevention and control
- 8:43A-23.3 Mobile vans
- 8:43A-23.4 Freestanding primary care outpatient facilities
- 8:43A-23.5 Small primary care outpatient facilities

SUBCHAPTER 24. CHRONIC DIALYSIS SERVICES

- 8:43A-24.1 Additional requirements
- 8:43A-24.2 Minimum program size and transfer agreements
- 8:43A-24.3 Patient services
- 8:43A-24.4 Qualifications of the medical director and medical records coordinator
- 8:43A-24.5 Nurse staffing
- 8:43A-24.6 Infection prevention and control
- 8:43A-24.7 Home care dialysis services
- 8:43A-24.8 Quality assurance
- 8:43A-24.9 Patient rights
- 8:43A-24.10 Physical plant requirements for all chronic dialysis facilities

SUBCHAPTER 25. COMPUTERIZED TOMOGRAPHY (CT), MAGNETIC RESONANCE IMAGING (MRI), AND RADIOLOGICAL SERVICES

- 8:43A-25.1 Additional requirements and exceptions
- 8:43A-25.2 Additional staffing
- 8:43A-25.3 Safety
- 8:43A-25.4 Physical plant; computerized tomography and magnetic resonance imaging services
- 8:43A-25.5 Physical plant; radiological services

SUBCHAPTER 26. DRUG ABUSE TREATMENT SERVICES

- 8:43A-26.1 Additional requirements and exceptions
- 8:43A-26.2 Smoking in facility
- 8:43A-26.3 Additional services
- 8:43A-26.4 Nurse staffing
- 8:43A-26.5 Drug abuse counseling services
- 8:43A-26.6 Designation of consultant pharmacist
- 8:43A-26.7 Medical records
- 8:43A-26.8 Notices
- 8:43A-26.9 Employee health

SUBCHAPTER 27. SATELLITES OF LICENSED AMBULATORY CARE FACILITIES

- 8:43A-27.1 Additional requirements and exceptions
- 8:43A-27.2 On-site inspection
- 8:43A-27.3 Appointment of administrator
- 8:43A-27.4 Patient care policies
- 8:43A-27.5 Medical records

SUBCHAPTER 28. BIRTH CENTERS

- 8:43A-28.1 Additional requirements
- 8:43A-28.2 Service restrictions
- 8:43A-28.3 Structural organization
- 8:43A-28.4 Designation of the clinical director
- 8:43A-28.5 Clinical director's responsibilities
- 8:43A-28.6 Physician consultation
- 8:43A-28.7 Additional policies and procedures
- 8:43A-28.8 Additional patient care services
- 8:43A-28.9 Labor and delivery patient services
- 8:43A-28.10 Newborn medical records
- 8:43A-28.11 Maternal-fetal transport and neonatal transport
- 8:43A-28.12 Supplies and equipment
- 8:43A-28.13 Additional quality assurance

SUBCHAPTER 29. EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES

- 8:43A-29.1 Additional requirements
- 8:43A-29.2 Additional staffing
- 8:43A-29.3 Safety

- 8:43A-29.4 Physical plant; extracorporeal shock wave lithotripsy services

APPENDIX A. DRUG AND ALCOHOL ADMISSION RECORD; DISCHARGE RECORD

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.

Amended by R.1996 d.341, effective July 15, 1996.
See: 28 N.J.R. 1364(a), 28 N.J.R. 3560(a).

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 intrapartum 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 intrapartum 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.

"Comprehensive rehabilitation agency" means an ambulatory care facility which provides at least medical, physical therapy, and social or psychological services in a coordinated manner.

"Conspicuously posted" means placed at a location within the facility accessible to and seen by patients and the public.

"Contamination" means the presence of an infectious or toxic agent in the air, on a body surface, or on or in clothes, bedding, instruments, dressings, or other inanimate articles or substances, including water, milk, and food.

"Controlled Dangerous Substances Acts" means the Controlled Substances Act of 1970 (Title II, Public Law 91-513) and the New Jersey Controlled Dangerous Substances Act of 1970, N.J.S.A. 24:21-1 et seq.

"Counseling" means provision of information intended to direct the behavior of a patient. Counseling services include, but are not limited to, dietary counseling, social work, and/or drug counseling services.

"Current" means up-to-date, extending to the present time.

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