

CHAPTER 43A

**MANUAL OF STANDARDS FOR LICENSURE
OF AMBULATORY CARE FACILITIES**

Authority

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

Source and Effective Date

R.1993 d.443, effective August 16, 1993.
See: 25 N.J.R. 757(b), 25 N.J.R. 4140(a).

Executive Order No. 66(1978) Expiration Date

Chapter 43A, Manual of Standards for Licensure of Ambulatory Care Facilities, expires on August 16, 1998.

Chapter Historical Note

Chapter 43A, Ambulatory Care Facilities, became effective May 26, 1976 as R.1976 d.165. See: 8 N.J.R. 117(a), 8 N.J.R. 282(b). Amendments became effective December 9, 1976 as R.1976 d.357. See: 8 N.J.R. 462(b), 8 N.J.R. 551(a).

1977 Revisions: Amendments became effective April 21, 1977 as R.1977 d.140. See: 9 N.J.R. 80(a), 9 N.J.R. 222(a). Further amendments became effective August 4, 1977 as R.1977 d.253. See: 9 N.J.R. 220(b), 9 N.J.R. 366(c).

1978 Revisions: Amendments became effective August 9, 1978 as R.1978 d.274. See: 10 N.J.R. 385(a). Further amendments became effective September 18, 1978 as R.1978 d.338. See: 10 N.J.R. 329(c), 10 N.J.R. 430(c). Further amendments became effective October 24, 1978 as R.1978 d.375. See: 10 N.J.R. 329(c), 10 N.J.R. 485(a). Further amendments became effective November 20, 1978 as R.1978 d.398. See: 10 N.J.R. 385(a), 10 N.J.R. 536(d).

1979 Revisions: Amendments became effective January 1, 1979 as R.1978 d.425. See: 10 N.J.R. 483(b), 11 N.J.R. 15(d). Further amendments became effective May 1, 1979 as R.1979 d.116. See: 11 N.J.R. 65(a), 11 N.J.R. 180(b). Further amendments became effective July 5, 1979 as R.1979 d.239. See: 11 N.J.R. 234(a), 11 N.J.R. 331(b). (The expiration date for Subchapter 14 was extended by R.1979 d.489 filed December 14, 1979. See: 11 N.J.R. 547(a), 12 N.J.R. 16(b). The expiration was further extended by R.1980 d.273. See: 12 N.J.R. 407(c).) Further amendments became effective December 1, 1979 as R.1979 d.406. See: 11 N.J.R. 330(a), 11 N.J.R. 549(e).

1980 Revisions: Amendments became effective February 1, 1980 as R.1980 d.488. See: 11 N.J.R. 546(c), 12 N.J.R. 16(a). Further amendments became effective March 3, 1980 as R.1980 d. 39. See: 11 N.J.R. 620(b), 12 N.J.R. 76(c). Further amendments became effective October 9, 1980 as R.1980 d.399. See: 12 N.J.R. 463(b), 12 N.J.R. 578(c).

1981 Revisions: Amendments became effective June 4, 1981 as R.1981 d.157. See: 13 N.J.R. 12(a), 13 N.J.R. 342(b).

1982 Revisions: Amendments became effective August 16, 1982 as R.1982 d.278. See: 13 N.J.R. 810(a), 14 N.J.R. 916(e).

1983 Revisions: Amendments became effective March 7, 1983 as R.1983 d.66. See: 14 N.J.R. 1273(a), 15 N.J.R. 336(a). Further amendments became effective March 21, 1983 as R.1983 d.92. See: 15 N.J.R. 9(a), 15 N.J.R. 440(d). Further amendments became effective March 7, 1983 as R.1983 d.66. See: 14 N.J.R. 1273(a), 15 N.J.R. 336(a). The chapter was readopted pursuant to Executive Order 66(1978) effective October 3, 1983 as R.1983 d.427. See: 15 N.J.R. 994(a), 15 N.J.R. 1662(a).

1984 Revisions: Readopted R.1984 d.497, filed October 18, 1984. See: 16 N.J.R. 2208(a), 16 N.J.R. 3031(a). Further amendments became effective November 5, 1984 as R.1984 d.497. See: 16 N.J.R. 2208(a), 16 N.J.R. 3031(a).

1985 Revisions: Amendments became effective February 4, 1985 as R.1985 d.26. See: 16 N.J.R. 3125(a), 17 N.J.R. 285(a). This chapter, which contained abortion rules in Subchapter 8, was repealed and new rules became effective September 3, 1985 as R.1985 d.438. See: 16 N.J.R. 3254(a), 17 N.J.R. 2110(b).

Petition: Petition to amend Manuals of Ambulatory Care Facilities concerning advertising by those facilities. See: 19 N.J.R. 306(d), 19 N.J.R. 570(b). Pursuant to Executive Order No. 66 (1988), Chapter 43A 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 was readopted as R.1993 d.443. See: Source and Effective Date. Existing Subchapters 1 through 11 and 13 through 19 were repealed by R.1993 d.443 and new subchapters were adopted, including Subchapters 20 through 29, effective September 7, 1993. Existing Subchapter 12 was amended by R.1993 d.443, effective September 7, 1993. See: 25 N.J.R. 757(b), 25 N.J.R. 4140(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

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 Application for licensure
- 8:43A-21.3 Medical staff to be provided
- 8:43A-21.4 Medical history
- 8:43A-21.5 Medical records

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**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 surgical, 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 rehabilitation agencies, 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 estab-

lishing 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:

“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 which provides preventive, diagnostic, and treatment services to persons who come to the facility to receive services and depart from the facility on the same day.

“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 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.

“Disinfection” means the killing of infectious agents outside the body, or organisms transmitting such agents, by chemical and physical means, directly applied.

“Documented” means written, signed, and dated.

“Drug” means a substance as defined in the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39. The word “medication” is used interchangeably with the word “drug” in this chapter.

“Drug abuse treatment services” means methadone detoxification, methadone maintenance, and/or drug-free counseling programs.

“Drug administration” means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures. The complete procedure of administration includes removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the prescriber’s orders, giving the individual dose to the patient, seeing that the patient takes it (if oral), and recording the required information, including the method of administration.

“Epidemic” means the occurrence in a facility of one or more cases of an illness in excess of normal expectancy for that illness, derived from a common or propagated source.

“Family planning services” means comprehensive reproductive health care services including contraception, pregnancy detection, options counseling, diagnosis and/or treatment of sexually transmitted diseases, routine gynecological and cancer screening services, health promotion activities, and Level I infertility services. Family planning services may also include prenatal and postpartum care, other gynecological services including colposcopy and cryotherapy, menopausal services, and/or Level II and III infertility care. Family planning services do not include termination of pregnancy.

“Full-time” means relating to a time period established by the facility as a full working week, as defined and specified in the facility’s policies and procedures.

“Governing authority” means the organization, person, or persons designated to assume legal responsibility for the management, operation, and financial viability of the facility.

“Health care facility” means a facility so defined in N.J.S.A. 26:2H-1 et seq.

“Hospital” means a health care facility as defined in the Licensing Standards for Hospitals, N.J.A.C. 8:43G.

“Job description” means written specifications developed for each position in the facility, containing the qualifications, duties and responsibilities, and accountability required of employees in that position.

“Licensed nursing personnel” (licensed nurse) means registered professional nurses or practical nurses licensed by the New Jersey State Board of Nursing.

“Maternal and Child Health Consortium (MCHC)” means a voluntarily formed non-profit organization, consisting of all inpatient or ambulatory perinatal and pediatric care providers and related community organizations in a maternal and child health service region, as described at N.J.A.C. 8:35A.

“Maternal and child health service region” means the perinatal and pediatric service delivery area described at N.J.A.C. 8:33C.

“Medical record” means all records in the facility which pertain to the patient’s health care.

“Medication” means a substance as defined by the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39. The word “drug” is used interchangeably with the word “medication” in this chapter.

“Monitor” means to observe, watch, or check.

“Plan of care” means a written plan which is based upon the patient assessments performed by all services participating in the patient’s care and which includes care and treatment to be provided. Each professional discipline which provides care to the patient develops its own portion of the plan of care.

“Prescriber” means a person who is authorized to write prescriptions in accordance with Federal and State laws.

“Primary care” means the provision by a health care facility of preventive, diagnostic, treatment, management, and reassessment services to individuals with acute or chronic illness. The term is used in reference to facilities providing family practice, general internal medicine, general pediatrics, obstetrics, gynecology, and/or clinical preventive services, including community health centers providing comprehensive primary care. Comprehensive primary care may include the provision of sick and well care to all age groups, from perinatal and pediatric care to geriatric care. Primary care is further characterized by the fact that it represents the initial point of contact between an individual and the health care system, by the assumption of responsibility for the person regardless of the presence or absence of disease, by the ongoing responsibility for coordination of medical care for the person, by its family-centeredness, and by its community orientation.

“Satellite” means an affiliate of a separately licensed ambulatory care facility. A satellite is located at a site distinct from that of the separately licensed ambulatory care facility, but shares the same governing authority and provides the same principal service as the separately licensed ambulatory care facility.

“Secondary care” means care delivered by a specialist or subspecialist following referral by the primary care source. This may include ambulatory or inpatient care.

"Signature" means at least the first initial and full surname and title (for example, R.N., L.P.N., D.D.S., M.D., D.O.) of a person, legibly written with his or her own hand. If electronic signatures are used, they shall be used in accordance with N.J.A.C. 8:43A-13.4.

"Staff education plan" means a written plan which describes a coordinated program for staff education for each service, including inservice programs and on-the-job training.

"Staff orientation plan" means a written plan for the orientation of each new employee to the duties and responsibilities of the service to which the employee has been assigned, as well as to the personnel policies of the facility.

"Sterilization" means a process of destroying all microorganisms, including those bearing spores, in, on, and around an object.

"Tertiary care" means specialized inpatient or outpatient care.

8:43A-1.4 Qualifications of the administrator of the ambulatory care facility

The administrator shall have a baccalaureate degree and two years of full-time, or full-time equivalent, administrative or supervisory experience in a health care facility. Each additional year of full-time, or full-time equivalent, administrative or supervisory experience and/or training in a health care facility may be substituted for each year of the four-year degree requirement. Four years of such experience and/or training may be used to satisfy the degree requirement.

8:43A-1.5 Qualifications of anesthesiologists

An anesthesiologist shall be a physician who has successfully completed a residency program in anesthesiology accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or 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.

8:43A-1.6 Qualifications of certified nurse midwife

Each certified nurse midwife shall meet the requirements of the New Jersey State Board of Medical Examiners at N.J.A.C. 13:35-2A.

8:43A-1.7 Qualifications of certified registered nurse anesthetists (CRNA)

Each certified nurse anesthetist shall meet the requirements of the New Jersey State Board of Nursing at N.J.A.C. 13:37-13.

8:43A-1.8 Qualifications of dentists

Each dentist shall be so licensed by the New Jersey State Board of Dentistry.

8:43A-1.9 Qualifications of dietitians

Each dietitian shall be registered or eligible for registration by the Commission on Dietetic Registration (Office on Dietetic Credentialing, 216 W. Jackson Boulevard—7th Floor, Chicago, Illinois 60606-6995).

8:43A-1.10 Qualifications of the director of nursing services

The director of nursing services shall be a registered professional nurse and shall have at least one year of full-time, or full-time equivalent, experience in nursing supervision and/or nursing administration in a licensed health care facility.

8:43A-1.11 Qualifications of drug counselors

(a) Each drug counselor shall:

1. Be certified by the Alcohol and Other Drugs of Abuse Counselor Certification Board of New Jersey, Inc. (90 Monmouth Street, Suite One, Red Bank, NJ 07701);
2. Be certified by the American Academy of Health Care Providers in the Addictive Disorders (260 Beacon Street, Somerville, MA 02143);
3. Be a social worker, in accordance with N.J.A.C. 8:43A-1.27;
4. Have a baccalaureate degree in a social science and one year of full-time equivalent experience in drug abuse counseling; or
5. Be currently enrolled in a program leading to one of the credentials required by (a)1 through 4 above and under the supervision of a person who has one of the credentials required by (a)1 through 4 above and at least three years of experience in drug counseling.

8:43A-1.12. Qualifications of family practice physicians

A family practice physician shall be a physician who has successfully completed a residency program in family practice accredited by the Accreditation Council for Graduate Medical Education or a residency program in general practice approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Family Practice or the American Osteopathic Board of General Practice.

8:43A-1.13 Qualifications of licensed practical nurses

Each licensed practical nurse shall be so licensed by the New Jersey State Board of Nursing.

8:43A-1.14 Qualifications of the medical director

The medical director shall be a physician who has successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in a medical specialty related to services provided by the facility, or who is a diplomate of one of the certifying boards approved by the American Board of Medical Specialties or one of the certifying boards of the American Osteopathic Association in a medical specialty related to services provided by the facility. If the facility provides chronic dialysis services, the medical director shall be a nephrologist, in accordance with N.J.A.C. 8:43A-24.4(a).

8:43A-1.15 Qualifications of nephrologists

A nephrologist shall be a physician who has successfully completed a residency program in nephrology accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Internal Medicine or the American Osteopathic Board of Internal Medicine in the subspecialty of nephrology.

8:43A-1.16 Qualifications of nurse practitioners

Each nurse practitioner shall be so certified by the New Jersey State Board of Nursing.

8:43A-1.17 Qualifications of obstetrician-gynecologists

An obstetrician-gynecologist shall be a physician who has successfully completed a residency program in obstetrics/gynecology accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology.

8:43A-1.18 Qualifications of pediatricians

A pediatrician shall be a physician who has successfully completed a residency program in pediatrics accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Pediatrics or the American Osteopathic Board of Pediatrics.

8:43A-1.19 Qualifications of pharmacists

Each pharmacist shall be so registered by the New Jersey State Board of Pharmacy.

8:43A-1.20 Qualifications of physician assistants

Each physician assistant shall be so licensed by the New Jersey State Board of Medical Examiners.

8:43A-1.21 Qualifications of physicians

(a) Each physician shall be licensed or authorized by the New Jersey State Board of Medical Examiners to practice medicine in the State of New Jersey.

(b) For any of the rules in this chapter requiring a physician to be Board-certified within his or her medical specialty, it shall be deemed acceptable to possess Board-certification from a foreign Board within the specified medical specialty where the American Board offers reciprocity with or officially recognizes the foreign board-certification credential.

8:43A-1.22 Qualifications of podiatrists

Each podiatrist shall be so licensed by the New Jersey State Board of Medical Examiners.

8:43A-1.23 Qualifications of radiation physicists/health physicists

Each radiation physicist/health physicist shall meet the requirements for certification as a specialist in radiation safety by the American Board of Radiology or the American Association of Physicists in Medicine, or shall have a master's degree with a major in medical radiation physics, health physics or radiologic health.

8:43A-1.24 Qualifications of radiologic technologists

Each radiologic technologist shall be so licensed by the New Jersey State Department of Environmental Protection.

8:43A-1.25 Qualifications of radiologists

A radiologist shall be a physician who has successfully completed a residency program in radiology accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Radiology or the American Osteopathic Board of Radiology.

8:43A-1.26 Qualifications of registered professional nurses

Each registered professional nurse shall be so licensed by the New Jersey State Board of Nursing.

8:43A-1.27 Qualifications of social workers

Each social worker shall be certified or licensed by the New Jersey State Board of Social Work Examiners and shall comply with the Social Workers' Licensing Act of 1991 (N.J.S.A. 45:15BB-1 et seq.) and amendments thereto and with all rules of the New Jersey State Board of Social Work Examiners. Prior to the implementation by the Board of procedures for applying for certification or licensure, each social worker shall have a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education (1744 R Street NW, Washington, D.C. 20036).

8:43A-1.28 Qualifications of urologists

A urologist shall be a physician who has successfully completed a residency program in urology accredited by the Accreditation Council for Graduate Medical Education or a residency program in urological surgery approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Urology or the American Osteopathic Board of Surgery in the subspecialty of urological surgery.

Director

Licensing, Certification and Standards

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

Trenton, New Jersey 08625

SUBCHAPTER 2. LICENSURE PROCEDURES**8:43A-2.1 Certificate of need**

(a) According to N.J.S.A. 26:2H-1 et seq., and amendments thereto, a health care facility shall not be instituted, constructed, expanded, or licensed to operate except upon application for, and receipt of, a certificate of need issued by the Commissioner.

(b) Application forms for a certificate of need and instructions for completion may be obtained from:

Certificate of Need Program

Division of Health Planning and Resources Development

New Jersey State Department of Health

CN 360

Trenton, New Jersey 08625

1. Application forms for a certificate of need in the case of transfer of ownership may be obtained from:

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

Trenton, New Jersey 08625

(c) The facility shall implement all conditions imposed by the Commissioner as specified in the certificate of need approval letter. Failure to implement the conditions may result in the imposition of sanctions in accordance with N.J.S.A. 26:2H-1 et seq., and amendments thereto.

Case Notes

Certificate of need requirement for ambulatory care facilities compared to certificate requirement for drug rehabilitation centers; zoning ordinance liberally construed. *L & L Clinics, Inc. v. Irvington*, 189 N.J.Super. 332, 460 A.2d 152 (App.Div.1983), certification denied 94 N.J. 540, 468 A.2d 191 (1983).

8:43A-2.2 Application for licensure

(a) Following receipt of a certificate of need or a determination that a certificate of need is not required, any person, organization, or corporation desiring to operate an ambulatory care facility shall make application to the Commissioner for a license on forms prescribed by the Department. Such forms may be obtained from:

(b) The Department shall charge a nonrefundable fee of \$500.00 for the filing of an application for licensure of an ambulatory care facility and \$500.00 for the initial license and annual renewal thereof. The licensing fee permits a facility to offer one of the services or centers listed in N.J.A.C. 8:43A-2.3(a) below. The facility shall submit an additional nonrefundable fee of \$250.00 for each service or center listed in N.J.A.C. 8:43A-2.3(a) which is provided in addition to the principal service of the facility. For a single license, the total fee which may be assessed for the filing of an application for licensure and for the annual renewal of the license shall not exceed \$2,000.

1. The Department shall charge a nonrefundable fee of \$250.00 for the filing of an application for licensure of a satellite of a separately licensed ambulatory care facility and for the annual renewal of the satellite license. This fee permits a satellite to offer one of the services or centers listed in N.J.A.C. 8:43A-2.3(a) below. The satellite shall submit an additional nonrefundable fee of \$250.00 for each service or center listed in N.J.A.C. 8:43A-2.3(a) which is provided in addition to the principal service of the satellite. For a single satellite license, the total fee which may be assessed for the filing of an application for licensure of the satellite and for the annual renewal of the license shall not exceed \$2,000.

(c) Each applicant for a license to operate a facility shall complete all information requested on the licensure application. An appointment for a preliminary conference shall be requested with the Licensing, Certification and Standards Program to review the conditions for licensure and operation.

(d) All applicants must demonstrate that they have the capacity to operate an ambulatory care facility in accordance with the rules in this chapter. An application for a license may be denied if the applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances, rules and bylaws, and standards of health care are fit and adequate and that there is reasonable assurance that the health care facility will be operated in accordance with the standards required by these rules. The Department may consider an applicant's prior history in operating a health care facility either in New Jersey or in other states in making this determination. Any evidence of licensure violations representing a serious risk of harm to patients may be considered by the Department, as well as any record of criminal convictions representing a risk of harm to the safety or welfare of patients.

8:43A-2.3 Types of services requiring a license

(a) None of the following services or centers shall be provided by an ambulatory care facility unless the facility license indicates that the service is provided by the facility:

1. Surgical center;
2. Family planning services;
3. Birth center;
4. Chronic dialysis services;
5. Diagnostic radiological center and/or magnetic resonance imaging services;
6. Extracorporeal shock wave lithotripsy services;
7. Drug abuse treatment services;
8. Primary care services, including family practice, pediatric, and/or prenatal, postpartum, or gynecological services;
9. Comprehensive rehabilitation services; and
10. Abortion facility.

(b) The license issued by the Department shall specify the services which the facility is licensed to provide. The facility shall obtain a determination of the applicability of Certificate of Need rules prior to requesting that any service be added to the license. The facility shall provide only those services for which it is licensed or authorized to provide by the Department.

(c) Any person, organization, or corporation applying for a license to operate an ambulatory care facility shall specify on the application the services to be provided.

(d) As of the effective date of this chapter, each facility shall specify, upon annual renewal of its license, the types of services to be provided, if the facility wishes to change the specification of services on the facility license.

(e) If a facility wishes to add any health care service during the annual licensure period, including any health care service not listed in (a) above, the facility shall obtain the authorization of the Licensing, Certification, and Standards Program of the Department prior to providing the additional service. Such authorization shall be based upon compliance with this chapter, and may be contingent upon an on-site inspection by representatives of the Department. This rule applies regardless of whether or not it is determined that a Certificate of Need is required.

8:43A-2.4 Newly constructed or expanded facilities

(a) Any ambulatory care facility which intends to undertake any alteration, renovation, or new construction of the physical plant, whether a Certificate of Need is required or not, shall submit plans to the Health Facilities Construction Services of the Department for review and approval prior to

the initiation of any work, in accordance with N.J.A.C. 8:43A-19.

(b) The licensure application for a newly constructed or expanded facility shall include written approval of final construction of the physical plant by:

Health Facilities Construction Services
 Division of Health Facilities Evaluation and Licensing
 New Jersey State Department of Health
 CN 367
 Trenton, New Jersey 08625

(c) An on-site inspection of the construction of the physical plant shall be made by representatives of Health Facilities Construction Services to verify that the building has been constructed in accordance with the architectural plans approved by the Department.

8:43A-2.5 Surveys and temporary license

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the Health Facilities Inspection Program of the Department shall be conducted to determine if the facility complies with the rules in this chapter.

1. The facility shall be notified in writing of the findings of the survey, including any deficiencies found.
2. The facility shall notify the Health Facilities Inspection Program of the Department when the deficiencies, if any, have been corrected, and the Health Facilities Inspection Program will schedule one or more resurveys of the facility prior to occupancy.

(b) A temporary license may be issued to a facility when the following conditions are met:

1. A preliminary conference (see N.J.A.C. 8:43A-2.2(c)) for review of the conditions for licensure and operation, unless determined by the Department to be unnecessary, has taken place between the Licensing, Certification and Standards Program and representatives of the facility, who will be advised that the purpose of the temporary license is to allow the Department to determine the facility's compliance with N.J.S.A. 26:2H-1 et seq. and the rules pursuant thereto;
2. Written approvals are on file with the Department from the local zoning, fire, health and building authorities;
3. Written approvals of the water supply and sewage disposal system from local officials are on file with the Department for any water supply or sewage disposal system not connected to an approved municipal system; and

4. Survey(s) by representatives of the Department indicate that the facility complies with the rules in this chapter.

(c) No facility shall admit patients to the facility until the facility has the written approval and/or license issued by the Licensing, Certification and Standards Program of the Department.

(d) Survey visits may be made to a facility at any time by authorized staff of the Department. Such visits may include, but not be limited to, the review of all facility documents and patient records and conferences with patients.

(e) A temporary license may be issued to a facility for a period of six months and may be renewed as determined by the Department.

(f) The temporary license shall be conspicuously posted in the facility.

(g) The temporary license is not assignable or transferable, and it shall be immediately void if the facility ceases to operate or if its ownership changes.

8:43A-2.6 Full license

(a) A full license shall be issued on expiration of the temporary license, if surveys by the Department have determined that the facility is operated as required by N.J.S.A. 26:2H-1 et seq. and by the rules pursuant thereto.

(b) A license shall be granted for a period of one year or less, as determined by the Department.

(c) The license shall be conspicuously posted in the facility.

(d) The license is not assignable or transferable, and it shall be immediately void if the facility ceases to operate or if its ownership changes.

(e) The license, unless suspended or revoked, shall be renewed annually on the original licensure date, or within 30 days thereafter but dated as of the original licensure date. The facility will receive a request for renewal fee 30 days prior to the expiration of the license. A renewal license shall not be issued unless the licensure fee is received by the Department.

(f) The license may not be renewed if local rules, regulations, and/or requirements are not met, in accordance with the provisions of N.J.A.C. 8:43A-2.10(a).

8:43A-2.7 Conditional license

A conditional license may be issued to a health care facility providing a type or category of health care service neither listed in N.J.A.C. 8:43A-2.3(a) nor otherwise addressed by this chapter. The facility shall comply with the standards set forth as a condition of the license.

8:43A-2.8 Surrender of license

The facility shall notify each patient, each patient's physician, and any guarantors of payment at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of license. In such cases, the license shall be returned to the Licensing, Certification and Standards Program of the Department within seven working days after the voluntary surrender, revocation, non-renewal, or suspension of license.

8:43A-2.9 Waiver

(a) The Commissioner or his or her designee may, in accordance with the general purposes and intent of N.J.S.A. 26:2H-1 et seq. and the rules in this chapter, waive sections of these rules if, in his or her opinion, such waiver would not endanger the life, safety, or health of patients or the public.

(b) A facility seeking a waiver of these rules shall apply in writing to the Director of the Licensing, Certification and Standards Program of the Department.

(c) A written request for waiver shall include the following:

1. The specific rule(s) or part(s) of the rule(s) for which waiver is requested;
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility upon compliance;
3. An alternative proposal which would ensure patient safety; and
4. Documentation to support the request for waiver.

(d) The Department reserves the right to request additional information before processing a request for waiver.

8:43A-2.10 Action against a license

(a) If the Department determines that operational or safety deficiencies exist, it may require that all admissions to the facility or to services provided within the facility cease. This may be done simultaneously with, or in lieu of, action to revoke licensure and/or impose a fine. The Commissioner or his or her designee shall notify the facility in writing of such determination.

(b) The Commissioner may order the immediate removal of patients from a facility whenever he or she determines that there exists imminent danger to any person's health or safety.

(c) The provisions of this section shall apply to facilities with a temporary license and to facilities with a full license.

(d) The Commissioner may issue a penalty on a facility for violation of licensure requirements of this chapter pursuant to N.J.S.A. 26:2H-13 and 14.

1. Each employee tested shall be informed in writing by the facility of the results of his or her rubella screening test.

2. Each employee's personnel record shall contain documentation of all tests performed and the results.

3. A list shall be maintained of all employees who are seronegative and unvaccinated, to be used in the event that an employee is exposed to rubella and a determination is needed as to whether or not the employee may continue to work.

(c) Each employee born in 1957 or later shall be given a measles (rubeola) screening test using the hemagglutination inhibition test, or other rubeola screening test, within six months of the effective date of this chapter. Each new employee born in 1957 or later shall be given a measles (rubeola) screening test upon employment. An employee who can document receipt of a live measles vaccine on or after the first birthday, physician-diagnosed measles, or serologic evidence of immunity shall not be required to have a measles (rubeola) screening test.

1. Each employee tested shall be informed in writing by the facility of the results of his or her measles (rubeola) screening test.

2. Each employee's personnel record shall contain documentation of all tests performed and the results.

3. A list shall be maintained of all employees who are seronegative and unvaccinated.

(d) Each employee, including members of the medical staff employed by the facility, shall receive a Mantoux tuberculin skin test with five tuberculin units of purified protein derivative within six months of the effective date of this chapter. Each new employee shall be given a Mantoux tuberculin skin test upon employment. Subsequent tests shall be performed in accordance with facility policy. Employees who can document negative Mantoux skin test results (zero to nine millimeters of induration) within the last year, employees who can document positive Mantoux skin test results (10 or more millimeters of induration), employees who have received appropriate medical treatment for tuberculosis, and employees for whom a Mantoux skin test is medically contraindicated shall not be required to receive a Mantoux tuberculin skin test.

1. If the Mantoux tuberculin skin test reaction is between zero and nine millimeters of induration, the test shall be repeated one to three weeks later.

2. If the Mantoux tuberculin skin test reaction is 10 or more millimeters of induration, a chest X-ray shall be performed and, if necessary, followed by chemoprophylaxis or therapy.

(e) The policy and procedure manual of the facility shall address employee safety and shall include procedures for

the care of employees who become ill at the facility or who are injured at the facility.

8:43A-3.8 Reportable events

(a) The facility shall notify the Department immediately by telephone at (609) 588-7725, or at (609) 392-2020 after business hours, of any event occurring within the facility which jeopardizes the health or safety of patients or employees. Events which shall be reported to the Department include, but are not limited to, the following:

1. All fires, disasters, accidents or other unanticipated events which result in serious injury or death of patients or staff, in evacuation of patients from the facility, or in closure of the facility for six or more hours;

2. All deaths of patients occurring in the facility;

3. Occurrence of epidemic disease in the facility; and

4. All alleged or suspected crimes which endanger the life or safety of patients or staff and which have also been reported at the time of occurrence to the local police department.

(b) Events reported by telephone to the Department in accordance with this section shall be confirmed in writing within seven days of the event, unless the Department determines that a written report is unnecessary. The written report shall contain information concerning injuries to patients or staff, disruption of services, extent of damages, and corrective actions taken.

(c) Resignation or termination of employment of the administrator, and the name and qualifications of the administrator's replacement, shall be reported to the Department in writing within seven days of the resignation or termination.

8:43A-3.9 Notices

(a) The facility shall conspicuously post a notice that the following information is available in the facility during business hours to patients and the public:

1. All waivers granted by the Department;

2. The list of deficiencies from the last annual licensure inspection and certification survey report (if applicable), and the list of deficiencies from any valid complaint investigation during the past 12 months;

3. A statement of patient rights;

4. The names of the members of the governing authority; and the addresses to which correspondence may be sent; and

5. The hours of operation and the business hours of the facility.

8:43A-3.10 Information reportable to State Board of Medical Examiners

(a) In accordance with the Professional Medical Conduct Reform Act, P.L. 1989, c.300, the facility shall notify the Medical Practitioner Review Panel established by the New Jersey State Board of Medical Examiners if a practitioner who is employed by, who is under contract to render professional services to, or who has privileges at the facility:

1. Voluntarily resigns from the staff if the facility is reviewing the practitioner's conduct or patient care or has expressed, through any member of the medical or administrative staff, an intention to do so;

2. Voluntarily relinquishes any partial privileges to perform a specific procedure if the facility is reviewing the practitioner's conduct or patient care or has expressed, through any member of the medical or administrative staff, an intention to do so;

3. Has full or partial privileges summarily or temporarily revoked or suspended, permanently reduced, suspended or revoked, has been discharged from the staff or has had a contract to render professional services terminated or rescinded for reasons relating to the practitioner's incompetency, misconduct, or impairment;

4. Agrees to the placement of conditions or limitations on the exercise of clinical privileges or practice within the health care facility including, but not limited to, second opinion requirements, nonroutine concurrent or retrospective review of admissions or care, nonroutine supervision by one or more members of the staff, or the completion of remedial education or training;

5. Is granted a leave of absence pursuant to which the practitioner may not exercise clinical privileges or practice within the facility and if the reasons provided in support of the leave relate to any physical, mental, or emotional condition or drug or alcohol abuse, which might impair the practitioner's ability to practice with reasonable skill and safety; or

6. Is a party to a medical malpractice liability suit in which the facility is also a party and in which there is a settlement, judgement, or arbitration award.

(b) For the purposes of (a) above, "practitioner" means physician, medical resident or intern, or podiatrist.

(c) Notifications required by (a) above shall be provided within seven days of the date of the action, settlement, judgement or award and shall be submitted on forms approved by the Department of Health for that purpose. The facility shall submit a completed supplemental form to the New Jersey State Board of Medical Examiners if so requested by the Board.

8:43A-3.11 Reporting to professional licensing boards

The facility shall comply with all requirements of the professional licensing boards for reporting termination, suspension, revocation, or reduction of privileges of any health professional licensed in the State of New Jersey.

SUBCHAPTER 4. GOVERNING AUTHORITY

8:43A-4.1 Responsibility of the governing authority

(a) The facility shall have a governing authority which shall assume legal responsibility for the management, operation, and financial viability of the facility. The governing authority shall be responsible for, but not limited to, the following:

1. Services provided and the quality of care rendered to patients;

2. Provision of a safe physical plant equipped and staffed to maintain the facility and services;

3. Adoption and documented review of written laws, or their equivalent, in accordance with a schedule established by the governing authority;

4. Appointment, reappointment, assignment of privileges, and curtailment of privileges of health care professionals, and written confirmation of such actions;

5. Ensuring development and review of all policies and procedures in accordance with a schedule established by the governing authority;

6. Establishment and implementation of a system whereby patient and staff grievances and/or recommendations, including those relating to patient rights, can be identified within the facility. This system shall include a feedback mechanism through management to the governing authority, indicating what action was taken;

7. Determination of the frequency of meetings of the governing authority and its committees, or equivalent, conducting such meetings, and documenting them through minutes;

8. Delineation of the duties of the officers of any committees, or equivalent, of the governing authority. When the governing authority establishes committees, their purpose, structure, responsibilities, and authority, and the relationship of the committee to other entities within the facility, shall be documented;

9. Establishment of the qualifications of members and officers of the governing authority, the procedures for electing and appointing officers, and the terms of service for members, officers, and committee chairpersons or equivalent; and

10. Approval of the medical staff bylaws or equivalent.

8:43A-18.2 Quality assurance activities

(a) There shall be an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

(b) Evaluation of patient care throughout the facility shall be criteria-based, so that certain review actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

(c) The quality assurance process shall incorporate periodic review of patient medical records.

(d) The quality assurance process shall include evaluation by patients of care and services provided by the facility. If the families of patients are routinely involved in the care and services provided by the facility, the quality assurance process shall include a means for obtaining input from families of patients.

(e) The administrator shall follow up on the findings of the quality assurance program to ensure that effective corrective actions have been taken, including at least policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

(f) The quality assurance program shall identify and establish indicators of quality care specific to the facility, which shall be monitored and evaluated.

(g) The results of the quality assurance program shall be submitted to the governing authority at least annually and shall include at least deficiencies found and recommendations for corrections or improvements. Deficiencies which jeopardize patient safety shall be reported to the governing authority immediately.

SUBCHAPTER 19. PHYSICAL PLANT AND FUNCTIONAL REQUIREMENTS

8:43A-19.1 Physical plant general compliance for new construction or alteration

(a) New buildings and alterations and additions to existing buildings for freestanding ambulatory care facilities shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23-3.2, subchapters of the current model code of the Building Officials and Code Administrators International (BOCA), Inc. (4051 W. Flossmoor Road, Country Club Hills, IL 60477-5795), appropriate to Use Group B, as amended and supplemented, and the current edition of the Guidelines for Construction and Equipment of Hospital and Medical Facilities (The American Institute of Architects

Press, 1735 New York Ave., NW, Washington, D.C. 20006), as amended and supplemented, incorporated herein by reference.

(b) New buildings and alterations and additions to existing buildings for ambulatory care facilities which are part of an acute care hospital shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23-3.2, subchapters of the current model code of the Building Officials and Code Administrators International (BOCA), Inc. (4051 W. Flossmoor Road, Country Club Hills, IL 60477-5795), appropriate to Use Group I-2, as amended and supplemented, and the current edition of the Guidelines for Construction and Equipment of Hospital and Medical Facilities (The American Institute of Architect Press, 1735 New York Ave., NW, Washington, D.C. 20006), as amended and supplemented, incorporated herein by reference.

8:43A-19.2 Physical plant general compliance for construction or alteration completed prior to the effective date of this chapter

Existing buildings constructed or altered prior to the effective date of this chapter shall be in conformance with Federal, State, and local standards in effect at the time of construction, alteration, or approval of plans by the Department.

8:43A-19.3 Plan review fees

(a) Prior to any construction, plans shall be submitted for review and approval, in accordance with the provisions of this chapter, to:

Health Facilities Construction Services
Division of Health Facilities Evaluation and Licensing
New Jersey State Department of Health
CN 367
Trenton, New Jersey 08625

(b) Review fees shall be paid, pursuant to N.J.A.C. 8:31-1.1.

8:43A-19.4 Alterations and repairs

(a) If alterations or repairs costing in excess of 50 percent of the physical value of the structure are made within any period of 12 months, requirements for new structures shall apply to the entire structure, including those portions not altered or repaired.

(b) If alterations or repairs costing between 25 percent and 50 percent of the physical value of the structure are made within any period of 12 months, only the altered or repaired portions need to conform to the requirements for new structures.

(c) If alterations or repairs costing under 25 percent of the physical value of the structure are made within any

period of 12 months, the construction official and appropriate subcode officials shall determine to what degree the portions so altered or repaired shall be made to conform to the requirements for new structures.

8:43A-19.5 Provision for the handicapped

Facilities shall be available and accessible to the physically handicapped pursuant to the New Jersey Uniform Construction Code, N.J.A.C. 5:23-7, Barrier-Free Subcode, and P.L. 100-336, the Americans with Disabilities Act of 1990 and Accessibility Guidelines for Buildings and Facilities, as amended and supplemented, incorporated herein by reference. (Available from the Government Printing Office, Superintendent of Documents, Washington, D.C. 20402.)

8:43A-19.6 Common elements for ambulatory health care facilities

All new ambulatory health care facilities, except small facilities addressed at N.J.A.C. 8:43A-19.7, shall comply with Chapter 9, Section 9.2, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992-1993 edition, as amended, and other sections appropriate to the specific service(s) provided therein, all of which is incorporated herein by reference.

8:43A-19.7 Small ambulatory care facilities

Chapter 9, Section 9.4, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992-1993 edition, as amended, is incorporated by reference herein and shall apply to new small ambulatory care facilities. "Small ambulatory care facility" means a facility which provides ambulatory care services and in which the space and equipment are utilized by four or fewer workers at any one time.

SUBCHAPTER 20. FAMILY PRACTICE SERVICES

8:43A-20.1 Additional requirements

An ambulatory care facility which provides family practice services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter.

8:43A-20.2 Medical staff to be provided

If an ambulatory care facility provides family practice services, the medical director shall be a family practice physician or the facility shall have a family practice physician on the medical staff. The family practice physician shall be

available during the facility's hours of operation. ("Available" means capable of being reached.)

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

8:43A-21.1 Additional requirements and exceptions

(a) An ambulatory care facility which provides family planning, prenatal, postpartum, and/or gynecological services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter. If the facility also provides surgical or anesthesia services, then the facility shall also comply with N.J.A.C. 8:43A-12.

1. An ambulatory care facility which provides only family planning services need not comply with N.J.A.C. 8:43A-2.2(b) for the purpose of licensure.

2. The facility shall be a formal member of a Maternal and Child Health Consortium, in accordance with N.J.A.C. 8:33C.

8:43A-21.2 Application for licensure

The Department shall charge a nonrefundable fee of \$100.00 for the filing of an application for licensure of an ambulatory care facility which provides, primarily or solely, family planning services and for the annual renewal of the license. The corresponding fee for each satellite of the facility which also provides, primarily or solely, family planning services shall be \$100.00. If such a facility or satellite provides a service listed in N.J.A.C. 8:43A-2.3(a) as an additional, secondary service, the facility or satellite shall submit an additional nonrefundable fee of \$250.00 per additional service for the filing of the application for licensure and for the annual renewal of the license.

8:43A-21.3 Medical staff to be provided

If an ambulatory care facility provides prenatal, postpartum, gynecological, and/or family planning services, the medical director shall be an obstetrician-gynecologist or the facility shall have an obstetrician-gynecologist on the medical staff. The obstetrician-gynecologist shall be available during the facility's hours of operation. ("Available" means capable of being reached.)

8:43A-21.4 Medical history

In addition to complying with N.J.A.C. 8:43A-6.4(a), the facility shall obtain the patient's obstetrical and gynecological history, if appropriate, including a history of psychological and social problems.

8:43A-21.5 Medical records

(a) The complete medical record for prenatal patients shall include, but not be limited to, documentation of assessment of uterine growth, fetal heart tones, estimated delivery date, urine tests for protein, blood pressure, weight gain, and an updated assessment of obstetrical risk, and shall be in conformance with N.J.A.C. 8:33C-4.3.

(b) The facility shall establish and implement written policies and procedures regarding the transfer of patient information when the patient is transferred to another health care facility, or if the patient has been an inpatient and becomes an outpatient at the same facility, to ensure continuity of care. In the case of a prenatal patient, a copy or summary of the patient's prenatal medical record shall be transferred, no later than 34 weeks gestation, from the facility to the inpatient facility where delivery is to take place. The facility shall also request a copy or summary of the patient's labor, delivery and postpartum record from the inpatient facility prior to any scheduled postpartum visits.

SUBCHAPTER 22. PEDIATRIC SERVICES

8:43A-22.1 Additional requirements

(a) An ambulatory care facility which provides pediatric services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter.

1. The facility shall be a formal member of a Maternal and Child Health Consortium, in accordance with N.J.A.C. 8:33C.

8:43A-22.2 Medical staff to be provided

A facility which provides pediatric services shall have a pediatrician or family practice physician on the medical staff and available during the facility's hours of operation. ("Available" means capable of being reached.)

8:43A-22.3 Medical records

The complete medical record for pediatric patients shall include, but not be limited to, documentation of assessment of growth, including at least a record of weight and length or height, documentation of a basic developmental assessment, including sensory screenings, and a record of immunization.

SUBCHAPTER 23. PRIMARY CARE

8:43A-23.1 Additional requirements

(a) An ambulatory care facility which provides primary care services, as defined at N.J.A.C. 8:43A-1.3, shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter. If the facility provides family practice services, then the facility shall also comply with the rules in N.J.A.C. 8:43A-20. If the facility provides primary care to a pediatric population, then the facility shall also comply with the rules in N.J.A.C. 8:43A-22.

1. If a facility provides primary care services only, the requirement at N.J.A.C. 8:43A-8.2 for a registered profes-

sional nurse to be on the premises during the hours of operation may be satisfied by a physician, if permitted by the policies and procedures of the facility.

8:43A-23.2 Infection prevention and control

The administrator shall designate 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.

8:43A-23.3 Mobile vans

(a) If a facility wishes to provide services through use of one or more mobile vans, the facility shall obtain the prior authorization of the Licensing, Certification and Standards Program of the Department. Such authorization may be contingent upon an on-site inspection by representatives of the Department.

(b) Policies and procedures for the use of mobile vans in the provision of primary care services shall address at least patient care, control of drugs, medical records, and infection prevention and control.

8:43A-23.4 Freestanding primary care outpatient facilities

New freestanding facilities which provide primary care services, except small facilities addressed at N.J.A.C. 8:43A-23.5, shall comply with Chapter 9, Sections 9.1, 9.2, and 9.3, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992-1993 edition, as amended, incorporated herein by reference.

8:43A-23.5 Small primary care outpatient facilities

(a) Small primary care outpatient facilities may be located within existing commercial, residential, licensed child care, educational, or other types of buildings or may be small, freestanding, new or converted structures. "Small primary care outpatient facility" means a facility which provides primary care services and in which the space and equipment are utilized by four or fewer workers at any one time.

(b) New small primary care outpatient facilities shall comply with Chapter 9, Section 9.4, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992-1993 edition, as amended, incorporated herein by reference.

SUBCHAPTER 24. CHRONIC DIALYSIS SERVICES

8:43A-24.1 Additional requirements

Hospital facilities which provide renal dialysis services within the hospital shall comply with N.J.A.C. 8:43G-30.

All other ambulatory care facilities which provide chronic dialysis services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter.

8:43A-24.2 Minimum program size and transfer agreements

(a) A facility providing chronic dialysis services shall have at least nine stations. Facilities licensed prior to the effective date of this chapter shall have until January 1, 1994, to establish this minimum number of stations. In the case of new construction or renovation involving at least 25 percent of the physical plant, an open treatment area shall contain no more than 20 stations.

(b) A facility providing chronic dialysis services shall have a written transfer agreement with at least one hospital-based chronic dialysis unit with acute dialysis capacity and with at least one facility having a renal transplantation program.

8:43A-24.3 Patient services

(a) The facility's policy on dialyzer reuse shall be explained to all chronic dialysis patients, and the facility shall document each patient's decision regarding consent to dialyzer reuse. If the patient declines reuse, arrangements shall be made for the patient to receive single-use treatment in the facility.

(b) In addition to complying with N.J.A.C. 8:43A-6.4, the facility shall ensure that a medical history is obtained and a physical examination is performed for each chronic dialysis patient within seven days of initiation of treatment and that these are updated at least every five years.

(c) A written plan of care shall be developed for each chronic dialysis patient by a multidisciplinary team which includes, at least, a nephrologist, a transplant surgeon or designee, a registered professional nurse, a dietitian, and a licensed social worker or a social worker hired prior to 1976 who receives consultation from a licensed social worker. The plan of care shall specify goals and expected outcomes.

(d) The written plan of care for each chronic dialysis patient shall be discussed with the patient and/or family, implemented within four weeks of admission to the facility, reviewed by the multidisciplinary team at least every six months, and revised as needed.

(e) Each member of the multidisciplinary team shall enter clinical notes into the chronic dialysis patient's medical record.

(f) If a chronic dialysis patient is referred by, or transferred from, another health care facility, the facility providing chronic dialysis services shall provide the referring or transferring facility with copies of summaries of the patient's progress, a description of dietary care, and results of laboratory tests upon discharge from the facility providing chronic dialysis services or upon request.

(g) Chronic dialysis patients shall be dialyzed in chairs which can be inclined so that the patient's head is lower than his or her feet, except when the patient is dialyzed in a hospital bed.

8:43A-24.4 Qualifications of the medical director and medical records coordinator

(a) The medical director of a facility which provides chronic dialysis services shall be a nephrologist. A medical director designated prior to July 1, 1993, shall have the qualifications of a nephrologist as specified at N.J.A.C. 8:43A-1.15. A medical director designated on or after July 1, 1993, shall be a diplomate of either the American Board of Internal Medicine or the American Osteopathic Board of Internal Medicine in the subspecialty of nephrology.

(b) The coordinator of medical records designated in accordance with N.J.A.C. 8:43A-13.2 shall be a medical records practitioner or shall function in consultation with a person so qualified. The medical records practitioner shall:

1. Be certified or eligible for certification as a registered record administrator (RRA) or an accredited record technician (ART) by the American Medical Record Association (875 North Michigan Avenue, Suite 1850, John Hancock Center, Chicago, Illinois 60611); or

2. Be a graduate of a program in medical record science accredited by the Committee on Allied Health Education and Accreditation of the American Medical Association in collaboration with the Council on Education of the American Medical Records Association.

8:43A-24.5 Nurse staffing

(a) A facility providing chronic dialysis services shall have at least one registered professional nurse, licensed practical nurse, or trained technician on duty for every three patients receiving dialysis services on the premises. In all cases, there shall be at least one registered professional nurse on duty for the first nine patients receiving dialysis services on the premises and an additional registered professional nurse if the number of patients exceeds nine, including the registered professional nurse required by N.J.A.C. 8:43A-8.2.

(b) Members of the nursing staff of facilities which provide chronic dialysis services shall receive on-site training in renal dialysis techniques, as determined by the facility, before they are permitted to work without direct supervision.

(c) If home (self) care dialysis training services are provided, a registered professional nurse shall direct the home (self) care dialysis training program. Training of patients may be assigned to licensed practical nurses. In no case shall training be conducted by less than one licensed nurse for every two patients on the premises receiving home (self) care dialysis training.