

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Chapter 43A, Ambulatory Care Facilities, was repealed and Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was adopted as new rules by R.1985 d.438, effective September 3, 1985.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was readopted as R.1993 d.443, effective August 16, 1993, and Subchapters 1 through 11 and 13 through 19 were repealed and new Subchapters 1 through 11 and 13 through 29 were adopted by R.1993 d.443, effective September 7, 1993.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

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SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

8:43A-1.1 Scope

The rules in this chapter pertain to all health care facilities which provide ambulatory care services including, but not limited to, primary care, hospital outpatient, ambulatory surgery, family practice, family planning, outpatient drug abuse treatment, chronic dialysis, computerized tomography, magnetic resonance imaging, extracorporeal shock wave lithotripsy, and radiological services. These rules also pertain to abortion facilities, comprehensive outpatient rehabilitation facilities, and birth centers. Ambulatory care facilities provide preventive, diagnostic, and treatment services to persons who come to the facility to receive services and depart from the facility on the same day. The rules in this chapter constitute the basis for the licensure of ambulatory care facilities by the New Jersey State Department of Health.

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.

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.

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
PO Box 360
Trenton, New Jersey 08625-0360

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
PO Box 367
Trenton, New Jersey 08625-0367

(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:

Director
Licensing, Certification and Standards
Division of Health Facilities Evaluation and Licensing
New Jersey State Department of Health
PO Box 367
Trenton, New Jersey 08625-0367

(b) The Department shall charge separate nonrefundable fees for the filing of an application for licensure, and for each annual licensure renewal of an ambulatory care facility in accordance with the following schedule:

Service	Application	Renewal
1. Chronic dialysis	\$2,500	\$2,500
2. Ambulatory surgery	\$2,500	\$2,500
3. Magnetic resonance imaging	\$2,000	\$1,000
4. Computerized tomography	\$2,000	\$1,000
5. Family planning (principal)	\$1,200	\$ 200

Service	Application	Renewal
6. Family planning (satellite)	\$ 600	\$ 100
7. Abortion	\$1,750	\$ 750
8. Birth	\$1,750	\$ 750
9. ESWL	\$1,750	\$ 750
10. Comprehensive rehabilitation	\$1,750	\$ 750
11. Drug abuse treatment	\$1,750	\$ 750
12. Primary care (principal)	\$1,750	\$ 750
13. Primary care (satellite)	\$ 875	\$ 375

(c) The total application fee shall be calculated by adding together the individual fees, as set forth in (b) above, for each service sought to be included on the facility's license. The total application fee shall not exceed the maximum cap set forth at N.J.S.A. 26:2H-12, as may be amended from time to time.

(d) The total annual renewal fee shall be calculated by adding together the individual fees, as set forth in (b) above, for each service included on the facility's license. The total annual renewal fee shall not exceed the maximum cap set forth at N.J.S.A. 26:2H-12, as may be amended from time to time.

(e) In the event that an ambulatory care facility is at any time approved by the Commissioner to provide a service other than those specifically listed in this section, the application and license renewal fees for such service shall be \$1,750 and \$750.00, respectively, unless the Commissioner, by regulation, specifically designates some other fee(s).

(f) Only those ambulatory care facilities which provide family planning or primary care services shall be eligible to file an application for licensure of a satellite facility.

1. Each satellite facility shall be separately licensed.

2. A satellite facility shall be licensed to provide only family planning and/or primary care services.

(g) The Department shall charge a nonrefundable fee for the filing of an application to add services to an existing ambulatory care or satellite facility. The application fee for each service to be added shall correspond with the fee for that service as set forth in (b) above. The total application fee for the addition of services shall not exceed the maximum cap set forth at N.J.S.A. 26:2H-12, as may be amended from time to time.

(h) The Department shall charge a nonrefundable fee of \$250.00 for the filing of an application to reduce services at an existing ambulatory care or satellite facility.

(i) The Department shall charge a nonrefundable fee of \$1,000 for the filing of an application for the transfer of ownership of an ambulatory care or satellite facility.

(j) The Department shall charge a nonrefundable fee of \$250.00 for the filing of an application for the relocation of an ambulatory care or satellite facility.

(k) 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.

(l) 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.

(m) Each ambulatory care facility shall be assessed a biennial inspection fee in accordance with the schedule set forth below. This fee shall be assessed in the year the facility will be inspected, along with the annual licensure fee for that year. The fee shall be added to the initial licensure fee for new facilities. Failure to pay the inspection fee shall result in non-renewal of the license for existing facilities and the refusal to issue an initial license for new facilities. This fee shall be imposed only every other year even if inspections occur more frequently and only for the inspection required to either issue an initial license or to renew an existing license. This fee shall not be imposed for any other type of inspection.

Service	Inspection Fee
1. Chronic dialysis	\$2,000
2. Ambulatory surgery	\$2,000
3. Magnetic resonance imaging	\$1,000
4. Computerized tomography	\$1,000
5. Family planning (principal)	\$200
6. Family planning (satellite)	\$200
7. Abortion	\$1,000
8. Birth	\$200
9. ESWL	\$1,000
10. Comprehensive outpatient rehabilitation	\$1,000
11. Drug abuse treatment (outpatient)	\$300
12. Primary care (principal)	\$200
13. Primary care (satellite)	\$200
14. Megavoltage radiation oncology	\$2,000

Amended by R.1996 d.340, effective July 15, 1996.

See: 28 N.J.R. 2369(a), 28 N.J.R. 3559(a).

Amended by R.1998 d.579, effective December 7, 1998.

See: 30 N.J.R. 3633(a), 30 N.J.R. 4421(b).

In (b), increased fees in 1 and 2; and added (m).

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. Ambulatory surgery facility;
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 outpatient rehabilitation facility; 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.

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-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
PO Box 367
Trenton, New Jersey 08625-0367

(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, if the facility's ownership changes, or if the facility is relocated to a different site.

Amended by R.1996 d.340, effective July 15, 1996.
See: 28 N.J.R. 2369(a), 28 N.J.R. 3559(a).

(b) A certified nurse-midwife and/or physician shall develop and implement a plan of care, if needed, for each patient with the patient's participation. The plan shall include at least care and treatment to be provided for the duration of the pregnancy, including laboratory studies and provision for the patient's health, psychosocial and nutritional needs.

(c) Each patient shall have at least the following prenatal laboratory tests and diagnostic procedures performed:

1. Urinalysis for glucose and protein;
2. Hemoglobin and hematocrit repeated at 28 weeks;
3. Sickle cells preparation (when appropriate);
4. Rh factor and blood typing;

5. Serological test for syphilis at the first prenatal visit, and in the last trimester of pregnancy or at delivery. If the patient is exposed to an infected partner, a serological test for syphilis shall be performed no sooner than three weeks after exposure;

6. Papanicolaou smear at the first prenatal visit if not documented within the previous six months;

7. Tuberculin test with indicated follow-up if in close contact with a diagnosed case of tuberculosis or from a high-incidence area so designated by the Department;

8. Rubella titer. If this is negative, rubella vaccine with appropriate counseling regarding timing of future pregnancies shall be offered to the patient after delivery and prior to discharge from the birth center;

9. One hour glucose tolerance test at 28 weeks gestation, if indicated by risk factors;

10. Maternal serum alpha-fetoprotein testing offered at 15 to 20 weeks; and

11. Hepatitis B virus screen with appropriate follow-up.

(d) Each patient shall be individually counseled about her progress in pregnancy by a certified nurse-midwife, physician, or a registered professional nurse at every visit, and a progress note shall be recorded in the patient's medical record.

(e) Each patient shall be examined at least once a month during the first seven months of gestation. Thereafter, the patient shall be seen every two weeks until 36 weeks and once a week thereafter. The examination shall be performed by either a certified nurse midwife or a physician.

(f) The results of all tests performed during patient examinations shall be documented in the patient's medical record including at a minimum: blood pressure, weight, dipstick urine analysis for glucose and protein, uterine growth, fetal heart rate, abdominal inspection and palpation, any unusual symptoms reported by the patient, and any physical evidence of abnormality. Evaluation of nutritional status and breast and pelvic examinations shall be docu-

mented on a regular basis. The medical record shall be in conformance with N.J.A.C. 8:33C-4.3.

8:43A-28.9 Labor and delivery patient services

(a) All deliveries shall be attended by a certified nurse-midwife, an obstetrician or a family practice physician.

(b) There shall be a second staff member present whenever a patient in active labor is in the facility. This individual shall be a registered professional nurse or an additional certified nurse midwife or physician.

(c) There shall be a health professional certified in neonatal resuscitation present for each delivery.

(d) A complete physical examination of the newborn shall be completed within two hours after birth.

8:43A-28.10 Newborn medical records

(a) The newborn's medical record shall be maintained as a separate record and shall include at least:

1. The date and time of birth;
2. The birth weight and length and head circumference;
3. The condition of the newborn at birth, including the one- and five-minute Apgar scores, details of any physical abnormalities, and any pathological states observed and treatment given;
4. A copy of vital records;
5. Documentation of eye prophylaxis, administration of any other medication or treatment and response, administration of Vitamin K, and performance of inborn error and hearing screenings; and
6. A record of follow-up of mother and newborn following discharge from the birth center.

8:43A-28.11 Maternal-fetal transport and neonatal transport

(a) There shall be a formal transfer/transport agreement between the birth center and the affiliated community perinatal center identified at N.J.A.C. 8:43A-28.3(b).

(b) The birth center shall maintain a written compilation of indicators necessitating transfer and written agreement for acceptance of such transfer patients developed by the affiliated community perinatal center and its staff, in collaboration with the birth center and its staff.

(c) The birth center shall develop a system to ensure continuity of care between the birth center and the transfer hospital, including escort of the patient to the admitting facility by a clinical staff member of the birth center.

8:43A-28.12 Supplies and equipment

(a) The birth center shall be equipped with at least the following:

1. A scrub sink with elbow, wrist, knee, or foot control;
2. Equipment for administering intravenous solutions to adults and newborns;
3. A supply of intravenous solutions including plasma expanders and glucose;
4. Emergency drug supplies;
5. A sphygmomanometer, stethoscope, fetoscope, and thermometer;
6. An infant scale;
7. One sterile pack for use in each birth room with at least one additional pack available. There shall be a written schedule for resterilization;
8. At least one infant warmer. If only one infant warmer is available, it must be transportable into all birth rooms;
9. An infant transport incubator, if not provided by the emergency transport service;
10. Resuscitation equipment for mother and infant;
11. Oxygen with a selection of mask sizes; and
12. Intubation equipment, including laryngoscopes and endotracheal tubes appropriate for adults and newborns.

8:43A-28.13 Additional quality assurance

(a) The quality assurance program shall, in addition to the requirements at N.J.A.C. 8:43A-18, include the following:

1. Review of all transfers of mothers and neonates to hospital care to determine the appropriateness and quality of the transfer; and
2. Review of all problems or complications of pregnancy, labor and postpartum and the appropriateness of the clinical judgement of the practitioner in obtaining consultation and attending to the problem.

SUBCHAPTER 29. EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES

8:43A-29.1 Additional requirements

An ambulatory care facility which provides extracorporeal shock wave lithotripsy 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.

8:43A-29.2 Additional staffing

(a) In addition to providing other staff as required by the rules in this chapter, a facility providing extracorporeal shock wave lithotripsy services shall have at least the following staff:

1. A urologist who shall be able to arrive at the facility within 30 minutes of being called; and
2. An anesthesiologist who shall be able to arrive at the facility within 30 minutes of being called.

(b) Urologists participating in the provision of extracorporeal shock wave lithotripsy services shall be certified by the American Lithotripsy Society (13 Elm Street, Manchester, MA 01944) or the American Urological Association, Inc. (1120 North Charles Street, Baltimore, MD 21201).

8:43A-29.3 Safety

(a) A facility providing extracorporeal shock wave lithotripsy services shall comply with the following:

1. The policies and procedures of the facility shall identify the staff qualified to participate in the provision of lithotripsy services;
2. Lithotripters shall be inspected at least semiannually by a qualified person. Preventive maintenance shall be documented; and
3. The facility shall develop and implement operational policies addressing at least the following:
 - i. The maximum number of shocks and/or voltage allowable;
 - ii. Bilateral treatment;
 - iii. Females of childbearing age;
 - iv. Patient weight limitations; and
 - v. Patients with pacemakers.

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

(a) The lithotripsy suite of any facility which provides extracorporeal shock wave lithotripsy services shall conform with Chapter 9, Section 9.1B through I, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities (1987 edition, The American Institute of Architects Press) incorporated herein by reference, and shall contain at least the following components:

1. A treatment room, which shall have a minimum of 360 square feet of floor space exclusive of fixed cabinets and built-in shelves. Handwashing facilities shall be located within the treatment room;
2. A cystoscopy room, which shall have a minimum clear area of 250 square feet exclusive of fixed cabinets and built-in shelves. A scrub sink shall be located adjacent to the entrance of the cystoscopy room;

3. Patient holding, induction, and preparation room(s), which shall be equipped with cabinets and handwashing facilities;

4. Patient clothing change areas. The facility shall provide areas in which male and female patients may change from street clothes into appropriate attire and prepare for treatment. These areas shall contain lockers and toilet facilities;

5. A postanesthesia care unit, which shall be designed so as to provide clearance space of at least three feet between patient stretchers and between patient bedsides and adjacent walls. The postanesthesia care unit shall satisfy the requirements of N.J.A.C. 8:43A-12.15 and shall contain at least the following:

- i. A nurses station with charting facilities;
- ii. A medication distribution station with handwashing facilities;
- iii. Toilet facilities; and
- iv. A clean holding area or room for the storage of clean and sterile equipment and linens;

6. A reception and information counter and desk;

7. A waiting area with access to a telephone, toilet facilities, and a drinking fountain;

8. A clerical space or room for business transactions and record storage, which shall be separate from public areas for purposes of confidentiality;

9. An enclosed soiled workroom, which shall contain a clinical sink or equivalent flushing-type fixtures, a work counter, and a sink equipped for handwashing;

10. A clean workroom or clean supply room. The clean workroom shall contain a work counter, a sink equipped for handwashing, and space for clean and sterile supplies;

11. A staff lounge and toilet facilities. Separate or combined lounges for male and female staff shall be provided;

12. A clinical report preparation area, which may be accessible from the lounge area;

13. An equipment storage room; and

14. A janitors' closet, which shall contain a floor receptor or service sink and storage for housekeeping supplies and equipment.

(b) New facilities shall comply with (a) above and with subsequent amendments and supplements to the 1987 edition of the standards referenced therein, which are incorporated herein by reference.

Appendix A

New Jersey State Department of Health

A-3A-6
Jan. 91

DRUG AND ALCOHOL ADMISSION RECORD

H-4152

Name of Client (First, Middle Initial, Last)	Social Security Number	Telephone Number
Street Address	City	State Zip Code

1. Provider Number	2. Case # 1st 2nd 1st 2nd	3. Sex (M/F)	4. Birthdate (mmddyy)	5. In-House Case No. (optional)	6. Admission Date (mmddyy)
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IMPORTANT: After completion of above, separate the Admission Record (Parts 1 and 2) from the Discharge Record (Parts 3 and 4)
USE BALL POINT PEN ONLY. All * fields require coded responses; see codes on the reverse side.

7. Client Type*	8. Treatment Setting at Intake*	9. Is use of methadone planned as part of treatment? 1 [] Yes 2 [] No	10. Resid. Code Co. Municip.	11. Post Office Zip Code
-----------------	---------------------------------	---	---------------------------------	--------------------------

12. Living Arrangements (Check ALL that apply)

- | | | | |
|-----------------------|-------------------------|------------------------------|-------------------------|
| A [] Alone | D [] With Parent(s) | G [] With Foster Parent(s) | J [] In Group Quarters |
| B [] With Children | E [] With Spouse | H [] With Other Relative(s) | K [] Homeless |
| C [] With Sibling(s) | F [] Living as Married | I [] With Friend(s) | |

13. Legal Status (Check ALL that apply)

- | | | | |
|-------------------------------|-----------------|------------------------------|------------------------------|
| A [] No Legal Problem | C [] Probation | E [] DWI License Suspension | G [] DYFS/Family Court Case |
| B [] Case Pending (Criminal) | D [] Parole | F [] Jail/Prison Inmate | H [] Other-Specify _____ |

14. Household income Per Year (Enter: 000 if None; 999 if unknown)	15. Household Size (No. of Persons)	16. Race*	17. Indicate Hispanic Origin* (5 if not applicable)
\$ _____,000	_____	_____	_____

18. Marital Status*	19. Highest School Grade Completed	20. Is Client a Full-Time Student? 1 [] Yes 2 [] No	21. Employment Status*	22. Referral Source*
_____	_____	_____	_____	_____

23. Number of Past Drug/Alcohol Treatment Episodes:

(Enter: 00 if None; 99 if unknown)

24. Self-Help Groups Ever Participated In (Check ALL That Apply)

- | | |
|---------------------------|----------------------------|
| A [] None | C [] Alcoholics Anonymous |
| B [] Narcotics Anonymous | D [] Other |
- Specify: _____

25. Health Coverage*

- | |
|-------|
| A [] |
| B [] |

26. Reimbursement Source*

- | |
|-------|
| A [] |
| B [] |

Agencies receiving public funds should note instructions

27. Check all drugs USED within the past 6 months

- | | |
|------------------------------------|-------------------------------------|
| ___ A. Alcohol | ___ J. Benzodiazepines |
| ___ B. Heroin | ___ K. Other Tranquilizers |
| ___ C. Non-Prescription Methadone | ___ L. Barbiturates |
| ___ D. Other Opiates or Synthetics | ___ M. Other Sedatives or Hypnotics |
| ___ E. Cocaine/Crack | ___ N. PCP |
| ___ F. Marijuana/Hashish | ___ O. Other Hallucinogens |
| ___ G. Methamphetamine | ___ P. Inhalants |
| ___ H. Other Amphetamines | ___ Q. Over-the-Counter |
| ___ I. Other Stimulants | ___ R. Other |

28. Does Client Smoke Tobacco? If yes, How many cigarettes per day?

- | | | |
|---|----------|-------|
| 1 [] Yes | 2 [] No | _____ |
| No. = (Packs X 20)
Pipe = PP
Cigar = CC | | |

27a. Drugs ABUSED	Primary	Secondary	Tertiary
Drug* (Use code letters at left)			
Route of Administration* (see codes below)			
Frequency* (see codes below)			
Age at First Use (99 if unknown)			
ROUTE CODES:	FREQUENCY CODES:		
1 - Oral	1 - Not Used In Past Month		
2 - Smoking	2 - Less Than Weekly		
3 - Inhalation	3 - 1-2 Times Per Week		
4 - Intramuscular/ Sub-Cutaneous	4 - 3 to 6 Times Per Week		
5 - Intravenous	5 - Daily		
	6 - 2 or More Times Per Day		

29. SPECIAL USE	5	10	15	20	25	30	35
Name of Agency	Name of Worker						