CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES

Authority

N.J.S.A. 26:2H-5 and 26:2H-8.

Source and Effective Date

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

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1d, the expiration date of Chapter 43A, Manual of Standards for Licensing of Ambulatory Care Facilities, was extended by gubernatorial directive from November 16, 2007 to January 31, 2008. See: 39 N.J.R. 5340(a).

Chapter Historical Note

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

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

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

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

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

Chapter 43A, Ambulatory Care Facilities, was repealed and Chapter 43A, Manual of Standards for Ambulatory Care Facilities, was adopted as new rules by R.1985 d.438, effective September 3, 1985.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

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

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

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was readopted as R.1993 d.443, effective August 16, 1993, and Subchapters 1 through 11 and 13 through 19 were repealed and new Subchapters 1 through 11 and 13 through 29 were adopted by R.1993 d.443, effective September 7, 1993.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

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

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

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

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

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

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

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

Subchapter 24, Renal Dialysis, was repealed and adopted as new rules, and Subchapter 32, Other Services, was adopted as new rules by R.2005 d.278, effective September 6, 2005. See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).

Subchapter 33, Programs of All-Inclusive Care for the Elderly (PACE) Organizations, was adopted as new rules by R.2007 d.106, effective April 16, 2007. See: 38 N.J.R. 4154(a), 39 N.J.R. 1480(a).

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 43A, Manual of Standards for Licensing of Ambulatory Care Facilities, expires on November 16, 2007. See: 39 N.J.R. 2309(a).

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SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

8:43A-1.1 Scope

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

8:43A-1.2 Purpose

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

8:43A-1.3 Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"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.

"Medically indigent" means those individuals lacking third-party health or medical insurance coverage whose income is less than or equal to 200 percent of the value determined by the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"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.

"Operating room" means a room specifically dedicated to the performance of surgical cases which meets the State Uniform Construction Code at N.J.A.C. 5:23-3 and the Department's licensing requirements. For the purposes of this definition, rooms specifically dedicated to endoscopic and cystoscopic procedures are not considered operating rooms.

"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, and within 30 miles of, 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.

"Surgical facility" means a structure or suite of rooms which has the following characteristics:

1. One or more rooms dedicated for use as operating rooms, which are specifically equipped for the performance of surgery, designed and constructed to accommodate invasive diagnostic and surgical procedures;

2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and

3. Is not a surgical practice.

"Surgical practice" means a structure or suite of rooms which has the following characteristics:

1. No more than one room dedicated for use as an operating room which is specifically equipped to perform surgery, designed and constructed to accommodate invasive diagnostic and surgical procedures;

2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and

3. Established by a physician or physician professional association surgical practice solely for his/her/their private medical practice.

"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 anesthesiaology 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 speciality, 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 (Reserved.)

Repealed by R.2005 d.278, effective September 6, 2005.
See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).
Section was "Certificate of need".

8:43A-2.2 Application for licensure

(a) 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 the Department's website address www.state.nj.us/health/hcsa/hcsaforms.html or from:

Director
Certificate of Need and Acute Care Licensure Program
Division of Health Care Quality and Oversight
PO Box 360
Trenton, New Jersey 08625-0360

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

Service		Application	Renewal
1.	Chronic dialysis	$4,000	$4,000
2.	Ambulatory surgery	$4,000	$4,000
3.	Magnetic resonance imaging	$4,000	$4,000
4.	Computerized axial tomography	$4,000	$4,000
5.	Family planning (principal)	$1,200	$ 200
6.	Family planning (satellite)	$ 600	$ 100
7.	Abortion	$1,750	$ 750
8.	Birth center	$1,750	$ 750
9.	Extracorporeal shock wave lithotripsy	$4,000	$4,000
10.	Comprehensive outpatient rehabilitation	$1,750	$ 750
11.	Drug abuse treatment	$1,750	$ 750
12.	Primary care (principal)	$1,750	$ 750
13.	Primary care (satellite)	$ 875	$ 375
14.	Megavoltage radiation oncology	$4,000	$4,000
15.	Orthotripsy	$4,000	$4,000
16.	Positron emission tomography	$4,000	$4,000
17.	Sleep center	$4,000	$4,000
18.	PACE organization	$1,750	$ 750

(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 $3,500 and $2,500, 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 $375.00 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 $1,500 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 $375.00 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 for licensure under this chapter must demonstrate that they have the capacity to operate an ambulatory care facility in accordance with the rules of 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 shall consider an applicant's prior history in operating a health care facility either in New Jersey or in other states in making this determination for all facilities eligible for licensure under this chapter. Any evidence of licensure violations representing a serious risk of harm to patients shall be considered by the Department, as well as any record of criminal convictions representing a risk of harm to the safety and welfare of patients pursuant to the enforcement provisions as set forth at N.J.A.C. 8:43E-5.1.

(m) Each ambulatory care facility shall be assessed a biennial inspection fee in accordance with the schedule set forth in the table below.

1. This fee shall be assessed in the year the facility will be inspected, along with the annual licensure fee for that year.

2. The fee shall be added to the initial licensure fee for new facilities.

3. Failure to pay the inspection fee shall result in nonrenewal of the license for existing facilities and the refusal to issue an initial license for new facilities.

4. 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.

5. 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	$2,000
4. Computerized axial tomography	$2,000
5. Family planning (principal)	$200
6. Family planning (satellite)	$200
7. Abortion	$1,000
8. Birth center	$200.00
9. Extracorporeal shock wave lithotripsy	$2,000
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
15. Orthotripsy	$2,000
16. Positron emission tomography	$2,000
17. Sleep center	$1,000
18. PACE Organization	$200
19. Other	$1,000

Amended by R.2004 d.160, effective April 19, 2004.
See: 35 N.J.R. 4838(a), 36 N.J.R. 1962(a).
In (b), rewrote the table; in (e), (h), (i) and (j), increased fees; in (l), substituted "In accordance with N.J.A.C. 8:33-4.10(d)1 through 11, all" for "All"; in (m), rewrote the table.

Amended by R.2005 d.278, effective September 6, 2005.
See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).
In (a), added "the Department's website address ... or from" following "forms may be obtained from", and changed mailing address; rewrote (l).
Amended by R.2007 d.106, effective April 16, 2007.
See: 38 N.J.R. 4154(a), 39 N.J.R. 1480(a).
In (b), added table entry 18; and in (m), inserted designations 1 through 5, added new table entry 18, and recodified former entry 18 as 19.

Cross Reference

Health care facilities, hospitals assessed a per adjusted admission charge, ambulatory care services, see NJSA 26:2H-18.57.

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.

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 Plan Review Program of the Department of Community Affairs for review and

approval or, in cases of existing construction where no Department of Community Affairs review is required, to the Department's Certificate of Need and Acute Care Licensure Program for review to verify that the facility's physical plant is consistent with the licensure standards 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 a copy of the Certificate of Occupancy, Certificate of Continuing Occupancy or a Certificate of Approval issued by the municipality in which the facility has been constructed in accordance with the construction plan approval by:

Health Plan Review
Division of Codes and Standards
Department of Community Affairs
PO Box 815
Trenton, New Jersey 08625–0815
Telephone: 609-633-8151

(c) An on-site inspection of the construction of the physical plant shall be made by representatives of the Department's Acute Care Survey Program to verify that the building has been constructed in accordance with the architectural plans approved by the Department of Community Affairs or, in cases of existing construction where no Department of Community Affairs review is required, to verify that the facility's physical plant is consistent with the licensure standards at N.J.A.C. 8:43A-19.

Amended by R.2005 d.278, effective September 6, 2005.
See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).
Rewrote the section.

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 Acute Care Survey 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 Acute Care Survey Program of the Department when the deficiencies, if any, have been corrected, and the Acute Care Survey 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 Certificate of Need and Acute Care Licensure 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.2005 d.278, effective September 6, 2005.
See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).
In (a), substituted "Acute Care Survey" for "Health Facilities Inspection" throughout; in (c), substituted "Certificate of Need and Acute Care Licensure" for Licensing, Certification and Standards".

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

(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.

(e) The Commissioner may suspend or revoke the license of a facility for failure to correct any violation of this chapter posing an imminent harm to patients pursuant to N.J.S.A. 26:2H-14.

8:43A-2.11 Hearings

(a) If the Department proposes to suspend, revoke, deny, or refuse to renew a license or authorization, the licensee or applicant may request a hearing which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) Prior to transmittal of any hearing request to the Office of Administrative Law, the Department may schedule a conference to attempt to settle the matter.

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:43A-3.1 Provision of services

(a) The facility shall provide preventive, diagnostic, and/or treatment services to patients. Medical services and nursing services, as required by this chapter, shall be provided in the facility. Medical services, nursing services, counseling services, pharmaceutical services, and laboratory and radiological services shall be provided directly by the facility or through written agreement.

(b) The facility shall have a written agreement for services not provided directly by the facility. The written agreement shall specify each party's responsibilities. If the service is provided in the facility, the written agreement shall require that services be provided in accordance with the rules in this chapter. If the service is provided outside of the facility, the written agreement shall require the provision of written documentation to the facility, including, but not limited to, documentation of services rendered and recommendations made by the party providing the service.

8:43A-3.2 Compliance with laws and rules

(a) The facility shall comply with applicable Federal, State, and local laws, rules, and regulations.

(b) If a health care facility licensed by the Department provides ambulatory care services in addition to other health care services, the facility shall comply with the rules in this chapter and with the rules for licensure of facilities which provide the other health care services.

8:43A-3.3 Ownership

(a) The ownership of the facility and the property on which it is located shall be disclosed to the Department. Proof of this ownership shall be available in the facility or at a designated location. Any proposed change in ownership shall be reported to the Director of the Licensing, Certification and Standards Program of the Department in writing at least 30 days prior to the change and in conformance with requirements for Certificate of Need applications.

(b) No facility shall be owned, managed, or operated by any person convicted of a crime relating adversely to the person's capability of owning, managing, or operating the facility.

8:43A-3.4 Submission of documents and data

(a) The facility shall, upon request, submit in writing any documents which are required by the rules in this chapter to the Director of the Licensing, Certification and Standards Program of the Department.

(b) The facility shall collect and submit to the Department, upon request, at least the following statistical data:

1. Number of patient visits, by payment source;

2. Number of distinct patients served, by payment source;

3. Number of new patients accepted; and

4. Number of practitioners, by type and level, providing services in the facility.

8:43A–3.5 Personnel

(a) The facility shall develop written job descriptions and ensure that personnel are assigned duties based upon their education, training, and competencies, and in accordance with their job descriptions.

(b) All personnel who require licensure, certification, or authorization to provide patient care shall be currently licensed, certified, or authorized under the appropriate laws or rules of the State of New Jersey or under the applicable standards of the appropriate body.

(c) Staffing schedules shall be implemented to ensure continuity of care to patients. Provision shall be made for substitute staff with equivalent qualifications to replace absent staff members.

(d) The facility shall develop and implement a staff orientation plan and a staff education plan, including plans for each service and designation of person(s) responsible for training.

1. All personnel shall receive orientation at the time of employment and at least annual in-service education regarding, at a minimum, emergency plans and procedures, the infection prevention and control program, universal precautions, policies and procedures concerning patient rights, and, if appropriate, given the patient population of the facility, identification of cases of child abuse and/or elder abuse.

(e) At least one person who is currently certified in basic cardiac life support by the American Heart Association or the American Red Cross, or currently certified by the Department as an emergency medical technician—ambulance (EMT–A), shall be in the facility at all times during the facility's hours of operation. If a cardiac rehabilitation program is provided, at least one person who is currently certified in advanced cardiac life support by the American Heart Association shall be in the facility at all times during the facility's hours of operation.

8:43A–3.6 Policy and procedure manual

(a) A policy and procedure manual(s) for the organization and operation of the facility shall be developed, implemented, and reviewed at intervals specified in the manual(s). Each review of the manual(s) shall be documented, and the manual(s) shall be available in the facility to representatives of the Department at all times. The manual(s) shall include at least the following:

1. A written statement describing the program's treatment philosophy, objectives, and staffing patterns, and the services provided by the facility;

2. An organizational chart delineating the lines of authority, responsibility, and accountability for the administration and patient care services of the facility;

3. A description of the quality assurance program for patient care and staff performance, including methods for at least annual review of staff qualifications and credentials and of staff orientation and education;

4. Definition and specification of hours of operation, including all times in which patients are present in the facility, business hours, and full working week;

5. A system for referral of patients to sources of secondary and tertiary health care;

6. A requirement for at least one member of the medical staff to maintain admitting privileges at a hospital;

7. Policies and procedures for the maintenance of personnel records for each employee, including at least the employee's name, previous employment, educational background, credentials, license number with effective date and date of expiration (if applicable), certification (if applicable), verification of credentials, records of physical examinations, job description, records of staff orientation and staff education, and evaluations of job performance; and

8. Policies and procedures for complying with applicable statutes and protocols to report child abuse and/or neglect, abuse or mistreatment of elderly or disabled adults, sexual abuse, specified communicable disease, rabies, poisonings, and unattended or suspicious deaths. These policies and procedures shall include, but not be limited to, the following:

i. The designation of a staff member(s) to be responsible for coordinating the reporting of diagnosed and/or suspected cases of child abuse and/or neglect in compliance with N.J.S.A. 9:6–1 et seq., recording the notification to the Division of Youth and Family Services in the medical record, and serving as a liaison between the facility and the Division of Youth and Family Services;

ii. The notification of any suspected case of patient abuse or exploitation to the State of New Jersey Office of the Ombudsman for the Institutionalized Elderly, pursuant to N.J.S.A. 52:27G–7.1 et seq., if the patient is 60 years of age or older;

iii. The development of written protocols for the identification and the treatment of children and elderly or disabled adults who are abused and/or neglected; and

iv. The provision at least annually of education and/or training programs to appropriate persons regarding the identification and reporting of diagnosed and/or suspected cases of child abuse and/or neglect; sexual abuse; domestic violence; abuse of the elderly or disabled adult; and the facility's policies and procedures.

Note: Copies of N.J.S.A. 9:6–1 et seq. can be obtained from the local district office of the Division of Youth and Family Services (DYFS) or from the Office of Program Support, Division of Youth and Family Services, New Jersey State Department of Human Services, PO Box 717, Trenton, New Jersey 08625–0717.

(b) The policy and procedure manual(s) shall be available and accessible to all patients, staff, and the public.

8:43A–3.7 Employee health

(a) The policy and procedure manual of the facility shall include policies and procedures to ensure that physical examinations of employees are performed upon employment and subsequently. Policies and procedures shall specify the circumstances under which other persons providing direct patient care services shall receive a physical examination. Policies and procedures shall specify the content and the frequency of the examinations.

(b) Each employee who cannot document the result of a previous rubella screening test shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test approved by the Department. Each new employee who cannot document the result of a previous rubella screening test shall be given the rubella screening test upon employment. An employee who can document seropositivity from a previous rubella screening test or who can document inoculation with rubella vaccine shall not be required to have a rubella screening test.

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) Tuberculosis screening: The facility shall establish policies and procedures for the detection and control of the transmission of *M. tuberculosis* that include, but are not limited to, developing a Tuberculosis Exposure Control Plan (TB plan), according to the guidelines set forth in "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health–Care Facilities, 1994," incorporated herein by reference, as amended and supplemented, Morbidity and Mortality Weekly Report (MMWR), published by the Epidemiology Program Office Centers for Disease Control and Prevention, October 28, 1994, Volume 43, Number RR–13, p. i–132, pursuant to the Occupational Safety and Health Act (OSH Act) of 1970, incorporated herein by reference and available by contacting the Superintendent of Documents, US Government Printing Office, Washington, DC 20402–9325.

1. Newly hired employees: The facility shall establish policies and procedures that will identify a new employee's baseline status of exposure to *M. tuberculosis*. Upon employment, the facility shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees. Employees are defined for the purposes of this section as full and part-time employees, volunteer staff, and physicians, either salaried by the facility or with clinical privileges to provide medical care at the facility.

i. Employees with a "negative" (less than 10 mm of induration or less than five mm of induration if the individual is immunosuppressed) result following the first Mantoux skin test are administered a second test in one to three weeks.

ii. Employees with a "positive" (greater than 10 mm of induration or greater than five mm of induration if the individual is immunosuppressed) result following either the first or second test are referred for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease.

(1) The medical evaluation shall include, but is not limited to, a chest X-ray.

(2) The facility shall permit employees with positive Mantoux test results to begin working after the employee has submitted written medical clearance to the facility.

iii. Exceptions:

(1) Employees who provide documentation of negative results of a single Mantoux skin test performed within the 12 months preceding the start of employment shall receive only one Mantoux skin test upon hire.

(2) Employees with prior documentation of negative results of two Mantoux skin tests performed within 12 months of preceding start of employment, and without signs and symptoms of active tuberculosis, shall not be required to be tested upon hire; however, a Mantoux skin test shall be required within 12 months of the last tuberculin skin test.

(3) Employees who provide documentation of positive Mantoux skin test results shall be exempt from screening.

(4) Employees who provide documentation of having received and completed appropriate medical treatment for active tuberculosis disease or latent tuberculosis infection shall be exempt from screening.

2. Periodic screening of personnel: The facility shall establish policies and procedures for the periodic screening of Mycobacterium tuberculosis in eligible personnel, including, but not limited to:

i. Testing: The facility shall administer a Mantoux skin test to all tuberculin-negative employees annually at minimum. Frequency of testing shall be determined by the level of risk assigned by the facility's TB plan.

ii. Recordkeeping: The facility shall maintain records of the results of employee Mantoux tuberculin testing.

3. Further information: Questions regarding tuberculosis control may be directed to:

New Jersey Department of Health and Senior Services
Tuberculosis Program
PO Box 369
Trenton, NJ 08625–0369
(609) 588–7522

(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.

Amended by R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Rewrote (d).

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.

8:43A–3.12 Reporting requirements for ambulatory surgery facilities

(a) As part of the annual licensure renewal process, all ambulatory surgery facilities shall submit to the Department's licensing program an audited statement that the facility has complied with the access requirements specified in the facility's certificate of need approval letter during the preceding licensure period. The audited statement shall include, but not be limited to, the following:

1. Total surgical case volume;

2. Surgical case volume for care provided to Medicaid-eligible and medically indigent persons, and its percentage of the total surgical case volume;

3. The cost of providing surgical care to Medicaid-eligible and medically indigent persons, excluding costs associated with bad debt or partial payment for individuals who are not Medicaid-eligible or medically indigent, and its percentage of the total cost of providing care; and

4. A description of the facility's free-care and partial-pay programs, including criteria of eligibility for each.

(b) As of July 15, 1996, each newly licensed ambulatory surgery facility shall submit to the Department the report of a survey of the facility performed by an independent accreditation organization approved by the Department. Such organizations shall be approved on the basis of their demonstrated ability to perform an operational survey using stan-

dards substantially equivalent to or exceeding the Federal Conditions for Coverage at 42 C.F.R. 416. The survey shall be performed, and the report shall be submitted to the Department, within the 12 months immediately following receipt of a 12-month temporary license from the Department. A full license shall not be issued upon expiration of the temporary license unless the report of the independent survey is submitted in accordance with this rule. Ambulatory surgery facilities licensed prior to July 15, 1996 shall have until July 15, 1999 in which to be surveyed by an independent accreditation organization. Following submission of the initial report, each licensed facility shall submit a report of the most recent survey by an independent accreditation organization as part of the annual licensure renewal process. Such survey shall have been performed within three years of licensure renewal. The survey report shall include, but not be limited to, corrective actions recommended and/or undertaken.

1. Licensure shall not be conditioned upon attainment by the ambulatory surgery facility of "accreditation" or "certification" or other such status granted by the independent accreditation organization.

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.

SUBCHAPTER 5. ADMINISTRATION

8:43A-5.1 Appointment of administrator

The governing authority shall appoint an administrator who shall be accountable to the governing authority. The administrator, or an alternate who shall be designated in writing to act in the absence of the administrator, shall be available in the facility during its hours of operation.

8:43A-5.2 Administrator's responsibilities

(a) The administrator shall be responsible for, but not limited to, the following:

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;

2. Planning for, and administration of, the managerial, operational, fiscal, and reporting components of the facility;

3. Participating in the quality assurance program for patient care and staff performance;

4. Ensuring that all personnel are assigned duties based upon their education, training, competencies, and job descriptions;

5. Ensuring the provision of staff orientation and staff education; and

6. Establishing and maintaining liaison relationships and communication with facility staff and services, with support services and community resources, and with patients.

SUBCHAPTER 6. PATIENT CARE POLICIES AND SERVICES

8:43A–6.1 Establishment and implementation of policies and procedures

The facility shall establish and implement written patient care policies and procedures governing the services provided.

8:43A–6.2 Patient care policy committee

(a) The facility shall establish a patient care policy committee, or its equivalent, consisting of, but not limited to, the administrator, the medical director, and a representative of the nursing service. A representative of each service offered by the facility shall attend all patient care policy committee meetings in which policies or procedures for that particular service are developed or reviewed.

(b) All patient care policies and procedures shall be reviewed by the patient care policy committee, in accordance with a schedule established by the governing authority, at least triennially. Each review shall be documented.

8:43A–6.3 Policies and procedures

(a) Patient care policies and procedures shall facilitate continuity of care to patients and shall include, but not be limited to, policies and procedures concerning the following:

1. Services to be provided, including preventive, diagnostic, and treatment services;

2. Patient rights;

3. The referral of patients to other health care providers and the use of consultant services, in order to provide a continuum of care for the patient;

4. The provision of emergency and after-hours care and treatment, including a definition of emergency;

5. Methods for obtaining and documenting informed consent, including definition or a listing of types of procedures for which informed consent will be required;

6. Advance directives, including, but not limited to, the following:

i. The circumstances under which an inquiry will be made of adult individuals receiving surgical services, anesthesia services other than minor conduction block, or chronic dialysis services regarding the existence and location of an advance directive;

ii. Requirements for provision of a written statement of patient rights regarding advance directives, approved by the Commissioner or his or her designee, to such patients upon admission; and

iii. Requirements for documentation in the medical record;

7. Admission of patients, including limitations on admission based on diagnosis, type or degree of disability, medical condition, patient age, or other factors. These limitations shall not conflict with applicable Federal and State laws prohibiting discrimination in the admission of patients or in the provision of health care services;

8. The facility's registration and appointment system;

9. Follow-up of broken appointments, including specification of the circumstances under which such follow-up will be performed;

10. The provision of screening services, if offered, including indications for, and frequency of, such services;

11. Medical histories and physical examinations;

12. Initiation, implementation, review, and revision of a written plan of care, including indication of the types of patients for whom a plan of care will be written;

13. A system whereby, whenever possible, the patient is cared for by the same health care professionals;

14. Methods for ensuring visual and auditory privacy of patients;

15. Immunization records, if applicable;

16. Patient instruction and health education;

17. The provision of telephone consultation to patients during the facility's hours of operation;

18. Discharge, termination by the facility, transfer, and readmission of patients, including criteria for each;

19. The safe-keeping of patients' valuables, when required; and

20. Other activities, as required by this chapter.

(b) All patient care policies and procedures shall be available within the facility.

8:43A–6.4 Medical history and physical examination

(a) The facility shall specify in its policies and procedures the circumstances under which the patient's medical history will be obtained, the contents of the medical history, and the frequency of updating. The contents shall include at least past surgical procedures and medical/health conditions, allergies, adverse reactions to drugs, and current medications.

(b) The facility shall specify in its policies and procedures the circumstances under which a physical examination will be performed, the frequency, and the contents. The contents shall include at least an assessment of body systems.

8:43A–6.5 Instructions and information for patients

The facility shall provide printed and/or written instructions and information for patients, with multilingual instructions as indicated. Information shall include, but not be limited to, tests and/or procedures needed, possible compli-

cations, a telephone number to call when needed, and instructions for obtaining care in an emergency.

8:43A–6.6 Communication assistance

The facility shall provide interpretation services, when necessary, for patients who do not speak English and for patients who are deaf. The facility shall provide other communication assistance, as needed, for patients who are blind.

8:43A–6.7 Suitability of equipment and supplies

The facility shall provide equipment and supplies which are appropriate to the treatment needs of patients of the types and ages served by the facility.

8:43A–6.8 Financial arrangements

(a) Records shall be maintained of all financial arrangements with patients, with copies furnished to the patient. The policies and procedures of the facility shall specify the form of retention and the retention schedule.

(b) Patients shall be informed, in advance, of the fees which are charged by the facility for the types of services and supplies expected to be provided to the patient, on the basis of a predetermined fee schedule. The facility shall post the fee schedule or a notice that the schedule is available in the facility. Patients shall be notified if physician or other practitioner fees will be billed separately.

(c) Policies and procedures shall require physicians and other practitioners to disclose, in advance, any separate charges, upon request of the patient.

(d) No additional charges, expenses, or other financial liabilities shall be assessed in excess of the predetermined rate, except:

1. Upon written approval and authority of the patient, who shall be given a copy of the written approval; or

2. In the event of a health emergency involving the patient and requiring immediate, special services or supplies to be furnished during the period of the emergency.

(e) Agreements with third-party payors and/or other payors, referral systems for patients' financial assistance, and sources of financial assistance available to the patient shall be described for the patient.

(f) Any sliding fee scales or special payment plans established by the facility shall be described and shall be made available for the patient to review upon the patient's request.

8:43A–6.9 Smoking in facility

The facility shall become smoke-free within three months of the effective date of this section. "Smoke-free" means a total ban on smoking in the facility by employees, visitors, and patients. Prior to the time at which the facility becomes smoke-free, the policy of the facility regarding smoking in the facility shall be in accordance with N.J.S.A. 26:3D–1 et seq.

8:43A–6.10 Calibration of instruments

All instruments of measurement shall be calibrated in accordance with manufacturers' instructions. A record of instrument calibration shall be maintained.

8:43A–6.11 Acupuncture services

If the facility provides acupuncture services, such services shall be provided in accordance with N.J.S.A. 45:2C–1 et seq.

SUBCHAPTER 7. MEDICAL SERVICES

8:43A–7.1 Provision of medical services

Medical services, as required by this chapter, shall be provided in the facility. Medical services shall be provided directly by the facility or through written agreement. Patients may be referred to physicians outside of the facility for additional medical services as required to provide a continuum of care for the patient.

8:43A–7.2 Designation of medical director

The governing authority shall designate a physician to serve as medical director. The medical director shall designate, in writing, a physician to act in the absence of the medical director. The medical director, or his or her designee, shall be available to the facility at all times.

8:43A–7.3 Medical director's responsibilities

(a) The medical director shall be responsible for the direction, provision, and quality of medical services provided to patients. He or she shall be responsible for, but not limited to, the following:

1. Developing and maintaining written objectives, policies, a procedure manual, an organizational plan, and a quality assurance program for the medical service. All medical policies and procedures shall be reviewed at least annually;

2. Participating in planning and budgeting for the medical service;

3. Coordinating and integrating the medical service with other patient care services to provide a continuum of care for the patient;

(b) The postanesthesia care unit shall be maintained as a closed unit. Access to the postanesthesia care unit shall be in accordance with facility policies and procedures.

(c) All staff in the postanesthesia care unit shall be attired in scrub attire. Individuals who are permitted limited access shall be attired according to facility infection control policies.

(d) Equipment and services available in the postanesthesia care unit shall include at least: a crash cart with defibrillator, drugs, pulse oximetry, electrocardiographic monitoring, body temperature monitoring, equipment necessary for intubation and various means of oxygen delivery. Constant and intermittent suction, blood pressure monitoring, adequate lighting, peripheral nerve stimulator, immediate access to a ventilator and end-tidal carbon dioxide monitoring in accordance with N.J.A.C. 8:43A–12.17(g) shall be made available. Provisions to ensure the patient's privacy shall be maintained.

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

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

Recodified from N.J.A.C. 8:43A–12.15 and amended by R.2003 d.56, effective February 3, 2003.
See: 34 N.J.R. 224(a), 35 N.J.R. 857(a).
Former N.J.A.C. 8:43A–12.18, Exceptions for local anesthesia, recodified to N.J.A.C. 8:43A–12.21. Rewrote (b) though (d).

8:43A–12.19 Designation of consultant pharmacist

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

Recodified from N.J.A.C. 8:43A–12.16 by R.2003 d.56, effective February 3, 2003.
See: 34 N.J.R. 232(a), 35 N.J.R. 865(a).

8:43A–12.20 Physical plant

(a) New ambulatory surgical facilities shall comply with Chapter 9, Sections 9.1 and 9.2, and with Chapter 9, Section 9.5 and 9.9, Outpatient Surgical Facility, of the Guidelines for Design and Construction of Hospital and Health Care Facilities, 2001 edition, as amended, incorporated herein by reference. (American Institute of Architects Press, 1735 New York Ave., NW, Washington, D.C. 20006)

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

Recodified from N.J.A.C. 8:43A–12.17 and amended by R.2003 d.56, effective February 3, 2003.
See: 34 N.J.R. 224(a), 35 N.J.R. 857(a).
In (a), inserted "and 9.9" following "section 9.5" and substituted "Guidelines for Design and Construction of Hospital and Health Care Facilities, 2001 edition" for "Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992–1993 edition".

8:43A–12.21 Exceptions for local anesthesia

Facilities in which local anesthesia or minor conduction regional blocks only are administered are exempt from complying with the requirements for anesthesia services in this subchapter, except that such facilities shall comply with the following: N.J.A.C. 8:43A–12.1, 12.4(d), 12.5(f), 12.5(g), 12.6(a)1, 12.6(a)2, 12.6(a)4 and 12.6(a)6. The facility shall also comply with N.J.A.C. 8:43A–12.11(g), except that the frequency of determining and charting temperature, pulse, respiration and blood pressure may be determined by the facility and specified in the policies and procedures of the facility.

Recodified from N.J.A.C. 8:43A–12.18 and amended by R.2003 d.56, effective February 3, 2003.
See: 34 N.J.R. 224(a), 35 N.J.R. 857(a).
Rewrote the section.

SUBCHAPTER 13. MEDICAL RECORDS

8:43A–13.1 Maintenance of medical records

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

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

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

and immediate availability of medical record information through telephone and facsimile communications systems.

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

8:43A–13.2 Assignment of responsibility

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

8:43A–13.3 Contents of medical records

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

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

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

3. The diagnosis or medical impressions;

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

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

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

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

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

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

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

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

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

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

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

15. Documentation of any consultations ordered or provided;

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

17. Documentation regarding an advance directive, if applicable;

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

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

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

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

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

8:43A–13.4 Requirements for entries

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

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

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

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

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

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

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

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

(c) The medical record shall be completed within the time frame specified in the medical records policies and procedures, which shall be no longer than 30 days from the last treatment or discharge.

(d) The medical record shall be available to the facility's health care practitioners involved in the patient's care at all times during the hours of operation.

8:43A–13.5 Medical records policies and procedures

(a) The facility shall establish and implement written policies and procedures regarding medical records including, but not limited to, policies and procedures for the following:

1. The protection of medical record information against loss, tampering, alteration, destruction, or unauthorized use. The patient's written consent shall be obtained for release of medical record information;

2. The specific period of time, not to exceed 30 days, within which the medical record shall be completed following treatment or discharge; and

3. 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.

(b) A patient, the patient's legally authorized representative, or a third party insurer where permitted by law may request or authorize, in writing, that a copy of the patient's medical record be provided to one of them or released to a third party. The ambulatory care facility or its subcontractor shall furnish a legible, written copy of the record at a fee based on actual costs. ("Legally authorized representative" within this section means spouse, immediate next of kin, legal guardian, executor, or an individual with power of attorney.) A copy of the medical record from an individual admission shall be provided within 30 days of request, in accordance with the following:

1. The fee for copying records shall not exceed $1.00 per page or $100.00 per record for the first 100 pages. For records which contain more than 100 pages, a copying fee of no more than $0.25 per page may be charged for pages in excess of the first 100 pages, up to a maximum of $200.00 for the entire record;

2. In addition to per page costs, the following charges are permitted:

i. A search fee of no more than $10.00 per patient per request; and

ii. A postage charge of actual costs for mailing, not to exceed $5.00;

3. No charges shall be assessed other than those permitted in (b)1 and 2 above;

4. The facility shall establish a policy assuring access to copies of medical records for patients who do not have the ability to pay; and

5. The facility shall establish a fee policy providing an incentive for use of abstracts or summaries of medical records. The patient or his or her authorized representative, however, has a right to receive a full or certified copy of the medical record.

(c) The Department shall periodically reevaluate the reasonableness of the fee scale contained in (b) above. If the Department determines that a change to the fee scale is warranted, the Department shall propose an amendment to (b) above.

(d) Access by the patient to the medical record shall be limited only to the extent necessary to protect the patient. A verbal explanation for any denial of access shall be given to the patient or legal guardian by the physician, and there shall be documentation of this in the medical record. In the event that direct access to a copy by the patient is medically contraindicated (as documented by a physician in the patient's medical record), the medical record shall be made available to a legally authorized representative of the patient or the patient's physician.

8:43A–13.6 Preservation, storage, and retrieval of medical records

(a) All medical records shall be preserved in accordance with N.J.S.A. 26:8–5 et seq.

(b) If the facility plans to cease operation, it shall notify the Department in writing, at least 14 days before cessation of operation, of the location where medical records will be stored and of methods for their retrieval.

SUBCHAPTER 14. INFECTION PREVENTION AND CONTROL SERVICES

8:43A–14.1 Administrator's responsibilities

(a) The administrator, or designee, shall ensure the development and implementation of an infection prevention and control program.

(b) The administrator shall designate an infection control professional who shall be responsible for the direction, provision, and quality of infection prevention and control services. The designated person shall be responsible for, but not limited to, developing and maintaining written objectives, policies and procedures, an organizational plan, and a quality improvement program for the infection prevention and control service. The infection control professional may

be a consultant; however, there must be a health care professional on site who is responsible for the day to day activities related to infection control.

(c) The infection control professional shall have education or training in surveillance, prevention, and control of nosocomial infections. The infection control professional shall be certified in infection control within five years of beginning practice of infection control and shall maintain certification through the Certification Board of Infection Control (CBIC).

Amended by R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
In (a), added ", or designee, " after "administrator"; rewrote (b); added (c).

8:43A–14.2 Infection control policies and procedures

(a) The facility shall establish an infection control committee which shall include the medical director, the infection control professional, and representatives from at least administration and the nursing service. If this facility is owned or operated by an acute care hospital, then the facility may participate in the hospital's infection control program.

(b) The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1. In accordance with N.J.A.C. 8:57 (Communicable Diseases), a system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility;

2. Identifying and reporting of HIV/AIDS as specified in N.J.A.C. 8:57–2, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus;

3. A system for identifying and monitoring nosocomial infections, in conformance with the "CDC Definitions for Nosocomial Infections, 1988" (order number PB 88–187117) incorporated herein by reference;

4. Infection control practices, including universal precautions, in accordance with the Occupational Safety and Health Administration (OSHA) rule 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens, incorporated herein by reference;

5. Control measures or studies to be initiated following identification of an infection control problem;

6. Aseptic technique, employee health in accordance with N.J.A.C 8:43A–3.7, and staff training in regard to infection control;

7. Care of patients with communicable diseases;

8. Exclusion from work, and authorization to return to work, for personnel with communicable diseases; and

9. Surveillance techniques to identify sources and minimize transmission of infection.

NOTE: Centers for Disease Control publications can be obtained from:

National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

or

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Copies of the OSHA rule 29 CFR Part 1910.1030, which was published in the Federal Register on December 6, 1991, can be obtained from:

OSHA Office of Publications
U.S. Department of Labor
Room N3101
200 Constitution Ave., NW
Washington, DC 20210

Amended by R.2004 d.299. effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Rewrote the section.

8:43A–14.3 Infection prevention measures

(a) Infection prevention activities shall be based on the Centers for Disease Control and Prevention Guidelines, and Hospital Infection Control Practices Advisory Committee (that is, HICPAC) recommendations. An exception to the adoption of the following guidelines shall be allowed providing that there is a sound infection control rationale based upon scientific research or epidemiologic data. The following published guidelines and recommendations are incorporated herein by reference, as amended and supplemented include:

1. Guideline for Prevention of Catheter–Associated Urinary Tract Infections (1981);

2. Guideline for Prevention of Intravascular Device–Related Infections (Infection Control and Hospital Epidemiology 1996; 17:438–73 and American Journal of Infection Control 1996; 24:262–93);

3. Guidelines for Prevention of Surgical Site Infections (1999) (Infection Control and Hospital Epidemiology 1999; 20:247–278);

4. Guideline for Prevention and Control of Nosocomial Pneumonia (American Journal of Infection Control, August 1994; 22:247–92 and Infection Control and Hospital Epidemiology, September 1994; 15:587–627 and Respiratory Care, December 1994; 39:1191–1236);

5. Guideline for Handwashing and Hospital Environmental Control (1985);

6. Guideline for Infection Control in Hospital Personnel (1998);

7. Guideline for Isolation Precautions in Hospitals (Infection Control and Hospital Epidemiology 1996; 17:53–80 and the American Journal of Infection Control 1996; 24:24–52);

8. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities (Morbidity and Mortality Weekly Report 1994; 43:11–22); and

9. HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance (Infection Control and Hospital Epidemiology 1995; 16:105–113).

(b) The guidelines listed in (a) above are available from the National Technical Information Service (NTIS) by calling 1–800–553–6847 or writing the NTIS, 5285 Port Royal Road, Springfield, Virginia 22161. The complete set of the seven Guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention National Center of Infectious Diseases website at: http://www.cdc.gov/ncidod/hip. The HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance is available on the CDC website at: http://www.cdc.gov/ncidod/vancom.htm. CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: http://www.cdc.gov/ncidod/hip/aresist/mrsahcw.htm.

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).

8:43A–14.4 Sterilization of patient care items

(a) Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorporated herein by reference:

1. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46;

2. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use," ST 37;

3. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities," ST 58;

4. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Guidelines for the Selection and use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities," ST 33;

5. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office–Based, Ambulatory Care, Medical, Surgical and Dental Facilities," January 1998; ST–42R;

6. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings," ST 35;

7. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness," October 1998, ST 41R; and

8. Society of Gastroenterology Nurses and Associates (SGNA), "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes," (2000).

(b) The documents referenced in (a) above are reviewed and/or revised every five years or more frequently as needed; the most current document is to be used. The AAMI requirements can be obtained from: The Association for the Advancement of Medical Instrumentation, 3330 Washington Building, Suite 400, Arlington, VA 22209 or at the AAMI website at www.aami.org. SGNA's Standards and Guidelines are available from the Society of Gastroenterology Nurses and Associates, Inc., 401 North Michigan Ave., Chicago, Il 60611–4267, or at www.sgna.org.

(c) Emphasis shall be placed on cleaning of these devices prior to sterilization or disinfection. The selection and use of disinfection and/or sterilization methods for patient care items or equipment shall be divided into the following three categories:

1. Critical items are objects that enter sterile tissue or the vascular system. These instruments, excluding scopes, must be sterilized by a process that can demonstrate a sterility assurance level of 10^{-6}.

i. Laparoscopes, arthroscopes, and other scopes that enter normally sterile areas of the body shall be sterilized or given high-level disinfection after each use according to the manufacturers' written recommendations or according to policy established by the facility's infection control committee.

2. Semicritical items are objects which come into contact with mucous membranes or with skin that is not intact. Semicritical items require high level disinfection or

intermediate level disinfection. (At a minimum, the disinfectant must be labeled as tuberculocidal.)

3. Noncritical items are objects that come into contact with intact skin but not with mucous membranes. Noncritical items shall at a minimum be exposed to a low level disinfectant.

(d) The efficacy of chemicals used for high-level disinfection shall be verified by the use of a test method specific to the chemical if a valid and reliable test method is available and feasible for use in an ambulatory setting.

(e) At the completion of each sterilization cycle, the following documentation shall be recorded and maintained on site for at least one year:

1. Time, temperature and pressure readings shall be verified and the print out/chart initialed by the operator before items are removed; and

2. A record of each sterilization/disinfection load, including the date, load/cycle number and the specific contents of the load shall be retained for a least one year or per facility policy, whichever is greater.

(f) Each package shall be labeled with sterilization date and load number.

(g) The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment shall be readily available and followed by employees.

1. All hinged instruments shall be processed in an open position.

2. All instruments that can be disassembled shall be disassembled for decontamination and sterilization.

(h) Sterilized materials shall be stored, handled and transported to maintain sterility. Package integrity shall be maintained until used.

(i) Sterile supplies which bear an expiration date shall not exceed the shelf life date as recommended by the manufacturer of the packaging selected or the device contained therein.

1. A policy and procedure to retrieve and reprocess outdates shall be established and enforced.

(j) If the facility is using an event-related sterility program, the process shall include a continuous quality plan with documentation of facility compliance with the following:

1. Proper transportation of sterile product;

2. Proper storage conditions of sterile product;

3. Proper rotation of sterile product; and

4. Maintenance of sterile pack integrity.

(k) All sterilization equipment shall be installed and operated in accordance with the sterilizer manufacturer's written instructions.

(*l*) Single use patient care items shall be reprocessed under the following conditions:

1. The manufacturer provides written documentation for cleaning and sterilization of the item and the facility has the resources to meet those specifications;

2. Methods for processing single use patient care items conform with the following Food and Drug Administration regulations:

i. Premarket Notification, Registration and Listing shall comply with 21 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and

ii. Quality system regulations as specified in 21 CFR Part 807, incorporated herein by reference, as amended and supplemented; and

3. If the facility retains an outside firm to provide its sterile processing, a quality control program shall be established to ensure the delivery of a safe product as specified in the contract with the third party processor.

(m) Shared reprocessing by outside healthcare reprocessing centers shall meet the following standards:

1. Policies and procedures for all processing protocols shall be approved by all facilities in the network in conjunction with infection control managers.

2. Instruments and devices transported off site for processing shall be inventoried and pre-cleaned prior to transportation.

i. Soiled instruments shall be contained in impervious, closed containers which are either locked or sealed in covered carts.

3. All decontamination, assembly and sterilization shall be performed according to the device manufacturer's written recommendations.

i. Manufacturer's written instructions for processing of all specialty devices shall be obtained, followed and kept on file at the processing facility.

4. The following records shall be maintained at the processing facility:

i. Sterilization logs shall be maintained for all items sterilized; and

ii. Biological monitoring as specified in N.J.A.C. 8:43A–14.5(a).

5. Immediate notification shall be made to the receiving facility upon a positive biological result.

6. Transport of sterile product shall be performed using disinfected, impervious containers that are either locked or sealed in covered carts.

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Section was "Use and sterilization of patient care items".

8:43A–14.5 Care and use of sterilizers, ethylene oxide, peracetic acid, low temperature gas, plasma, and steam

(a) Biological monitoring with live spores, or an FDA approved equivalent, shall be performed as follows:

1. Ethylene oxide—in each load;

2. Peracetic acid—weekly;

3. Low temperature gas plasma—daily in the working load;

4. Steam sterilizers—weekly;

5. A biological monitor with live spores shall be performed following repair or breakdown of the above mentioned equipment; and

6. A biological monitor, or spore based enzyme, shall be used with each load containing implantables, and the implantable device shall not be used until the negative biological test is received.

(b) The biological indicator shall be applicable for the process used and shall be stored and used in accordance with the manufacturer's recommendations.

1. A rapid read out biological monitor must be incubated to obtain a spore kill reading. The length of incubation shall comply with the written instructions provided by the manufacturer of the biological indicator.

2. A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

i. Each package processed in steam;

ii. Each package processed in ethylene oxide;

iii. Each package processed in low temperature gas plasma; and

iv. Each load, as directed by the manufacturer, for peracetic acid.

3. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer.

4. In the event of positive biological test results on a sterilizer, effective corrective action shall be taken including retesting and recalls if indicated.

i. Documentation of actions taken shall be maintained on site.

ii. There shall be an established recall system in effect.

5. The individual responsible for reprocessing reusable medical instruments shall be certified by a national central service certification program upon hire or within two years of employment.

6. All personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection (NJDEP).

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Section was "Care and use of sterilizers".

8:43A–14.6 Maintenance of sterile processing environment

(a) The following environmental surfaces shall be maintained as follows in decontamination and clean processing areas:

1. Hard surface floors shall be kept clean.

2. Walls shall be cleaned of spills and splashes as necessary.

3. Ceilings, ventilation system vents, and sterilizer vents shall be clean and free from dust.

4. Storage shelves shall be kept clean.

5. All horizontal surfaces shall be disinfected each shift and as needed.

(b) There shall be separation between clean and contaminated work areas and activities.

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Section was "Regulated medical waste".

8:43A–14.7 Infection control quality improvement methods

The infection control professional shall develop and implement a program of quality improvement that is integrated into the facility quality improvement program and includes regularly collecting and analyzing data to help determine the effectiveness of infection control practices. When corrective actions need to be taken based on data collected, the infection control committee shall recommend, implement, and monitor those actions. The infection control professional shall supervise these quality improvement activities. These quality improvement activities shall be overseen by the continuous quality improvement program. (See Subchapter 18).

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).
Section was "Disposition of tissue".

SUBCHAPTER 15. EMERGENCY SERVICES AND DISASTER PLANS

8:43A–15.1 Disaster planning

(a) The facility shall have written emergency plans, policies, and procedures which shall include plans and proce-

dures to be followed in case of potential hazards that could necessitate an evacuation, including internal and external disasters such as fire, natural disaster, bomb threats, or industrial or radiological accidents.

(b) The written, comprehensive emergency plan shall be filed with the Department of Health, and the Department shall be notified when the plan is changed. Copies of emergency plans shall also be forwarded to both municipal and county emergency management officials for their review.

(c) Procedures for emergencies shall include at least:

1. Protocols for notification of emergency service providers and officials;

2. Locations of emergency equipment and alarm signals;

3. Evacuation routes;

4. Procedures for evacuating patients;

5. Identification of one or more facilities to which patients would be referred in the event of extended closure of the facility;

6. Procedures for reentry after evacuation;

7. Tasks and responsibilities assigned to all personnel and identification of the person in the facility designated to coordinate emergency activities;

8. Protocols for removal and return of records, medications, supplies, and equipment after evacuation; and

9. Alternative procedures if patients cannot be returned to the facility.

(d) The facility shall ensure that patients receive necessary services during the evacuation or other emergency.

(e) A written evacuation diagram that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be conspicuously posted throughout the facility.

(f) All employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and patient evacuation as part of their initial orientation and at least annually thereafter.

8:43A–15.2 Drills, tests, and inspections

(a) Drills of emergency plans shall be conducted on each shift at least quarterly. The facility shall maintain documentation of all drills, including the date, hour, description of the drill, participating staff, and signature of the person in charge. The drills on each shift shall include at least one drill for emergencies due to fire and one drill for emergencies due to disasters other than fire, such as storm, flood, other natural disaster, bomb threat, or radiological accident.

(b) The facility shall perform quarterly tests of the building's manual pull alarm system and shall maintain documentation of test dates, locations of manual pull alarms tested, persons testing the alarms, and results of the tests.

(c) Fire extinguishers shall be examined annually and maintained in accordance with manufacturers' requirements, National Fire Protection Association (N.F.P.A.) 10, as amended and supplemented, and N.J.A.C. 5:18, the New Jersey Uniform Fire Code.

(d) The facility shall request, at least annually, that a fire inspection be performed by the local fire code authority, and the request shall be documented. The date of inspection, the results, and the inspector or agent conducting the inspection shall be documented.

(e) There shall be at least a semiannual inspection of the fire detection system. The date of inspection, the results, and the inspector or agent conducting the inspection shall be documented.

(f) There shall be at least a semiannual inspection of the automatic sprinkler system, if applicable. The date of inspection, the results, and the inspector or agent conducting the inspection shall be documented.

(g) There shall be at least monthly testing of emergency lighting. A logbook shall be maintained which shall include the date of each test, the results, and the person conducting the test.

(h) There shall be an elevator inspection, if applicable, in accordance with N.J.A.C. 5:23–12.3 of the Elevator Safety Subcode. The date of inspection, the results, and the licensed official or inspector conducting the inspection shall be documented.

(i) There shall be at least an annual inspection of the heating and ventilation system. The date of inspection, the results, and the inspector or agent conducting the inspection shall be documented.

(j) The temperature of the hot water used in the facility shall be tested and documented in accordance with the policies and procedures of the facility.

8:43A–15.3 Emergency medical services

(a) The facility shall have written policies and procedures that are reviewed annually, revised as needed, and implemented as needed to meet medical emergencies based on the type of patients and cases that are typically treated at the facility.

(b) The facility shall be able to respond to medical emergencies occurring on the premises during its hours of operation.

(c) Emergency medical services not provided at the facility shall be provided by a hospital or hospitals by written agreement. The facility shall have a written plan for emergency transportation of patients.

(d) The facility shall have written policies and procedures regarding emergency kits and, if required, emergency carts which are appropriate to the patient population served by the facility and approved by the medical director. The policies and procedures shall be reviewed annually, revised as needed, and implemented, and shall:

1. Specify the locations, contents, frequency of checking contents (including expiration dates), and assignments of responsibility for checking contents; and

2. Ensure that emergency kits are secure but are not kept under lock and key.

(e) At least one person who is trained in the use of emergency equipment shall be available whenever there is a patient in the facility.

SUBCHAPTER 16. PATIENT RIGHTS

8:43A-16.1 Policies and procedures

(a) The facility shall establish and implement written policies and procedures regarding the rights of patients. These policies and procedures shall be available to patients, staff, and the public and shall be conspicuously posted in the facility.

(b) The staff of the facility shall receive in-service education concerning the implementation of policies and procedures regarding patient rights annually and as part of new employee orientation.

(c) The facility shall comply with all applicable State and Federal statutes and rules concerning patient rights.

8:43A-16.2 Rights of each patient

(a) Each patient receiving services in an ambulatory care facility shall have the following rights:

1. To be informed of these rights, as evidenced by the patient's written acknowledgement, or by documentation by staff in the medical record, that the patient was offered a written copy of these rights and given a written or verbal explanation of these rights, in terms the patient could understand. The facility shall have a means to notify patients of any rules and regulations it has adopted governing patient conduct in the facility;

2. To be informed of services available in the facility, of the names and professional status of the personnel providing and/or responsible for the patient's care, and of fees and related charges, including the payment, fee, deposit, and refund policy of the facility and any charges for services not covered by sources of third-party payment or not covered by the facility's basic rate;

3. To be informed if the facility has authorized other health care and educational institutions to participate in the patient's treatment. The patient also shall have a right to know the identity and function of these institutions, and to refuse to allow their participation in the patient's treatment;

4. To receive from the patient's physician(s) or clinical practitioner(s), in terms that the patient understands, an explanation of his or her complete medical/health condition or diagnosis, recommended treatment, treatment options, including the option of no treatment, risk(s) of treatment, and expected result(s). If this information would be detrimental to the patient's health, or if the patient is not capable of understanding the information, the explanation shall be provided to the patient's next of kin or guardian. This release of information to the next of kin or guardian, along with the reason for not informing the patient directly, shall be documented in the patient's medical record;

5. To participate in the planning of the patient's care and treatment, and to refuse medication and treatment. Such refusal shall be documented in the patient's medical record;

6. To be included in experimental research only when the patient gives informed, written consent to such participation, or when a guardian gives such consent for an incompetent patient in accordance with law, rule and regulation. The patient may refuse to participate in experimental research, including the investigation of new drugs and medical devices;

7. To voice grievances or recommend changes in policies and services to facility personnel, the governing authority, and/or outside representatives of the patient's choice either individually or as a group, and free from restraint, interference, coercion, discrimination, or reprisal;

8. To be free from mental and physical abuse, free from exploitation, and free from use of restraints unless they are authorized by a physician for a limited period of time to protect the patient or others from injury. Drugs and other medications shall not be used for discipline of patients or for convenience of facility personnel;

9. To confidential treatment of information about the patient. Information in the patient's medical record shall not be released to anyone outside the facility without the patient's approval, unless another health care facility to which the patient was transferred requires the information, or unless the release of the information is required and permitted by law, a third-party payment contract, or a peer review, or unless the information is needed by the New Jersey State Department of Health for statutorily authorized purposes. The facility may release data about the patient for studies containing aggregated statistics when the patient's identity is masked;

10. To be treated with courtesy, consideration, respect, and recognition of the patient's dignity, individuality, and right to privacy, including, but not limited to, auditory and visual privacy. The patient's privacy shall also be respected when facility personnel are discussing the patient;

11. To not be required to perform work for the facility unless the work is part of the patient's treatment and is performed voluntarily by the patient. Such work shall be in accordance with local, State, and Federal laws and rules;

12. To exercise civil and religious liberties, including the right to independent personal decisions. No religious beliefs or practices, or any attendance at religious services, shall be imposed upon any patient;

13. To not be discriminated against because of age, race, religion, sex, nationality, or ability to pay, or deprived of any constitutional, civil, and/or legal rights solely because of receiving services from the facility; and

14. To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care in accordance with N.J.A.C. 8:43E-6.

Amended by R.2005 d.278, effective September 6, 2005.
See: 37 N.J.R. 699(a), 37 N.J.R. 3348(a).
In (a)12, deleted "and" following "patient;"; in (a)13, substituted "; and" for "."; added (a)14.

8:43A-16.3 Notice

(a) The administrator shall provide all patients and/or their families upon request with the name, addresses, and telephone numbers of the following offices where complaints may be lodged:

Division of Health Facilities Evaluation and Licensing
New Jersey State Department of Health
PO Box 367
Trenton, New Jersey 08625-0367
Telephone: (609) 792-9770

and

State of New Jersey
Office of the Ombudsman for the Institutionalized Elderly
PO Box 808
Trenton, New Jersey 08625-0808
Telephone: (609) 624-4262

(b) The administrator shall also provide all patients and/or their families upon request with the names, addresses, and telephone numbers of offices where information concerning Medicare and Medicaid coverage may be obtained.

(c) Addresses and telephone numbers contained in (a) and (b) above shall be conspicuously posted throughout the facility, including, but not limited to, the admissions waiting area or room, the patient service area of the business office, and other public areas.

SUBCHAPTER 17. HOUSEKEEPING, SANITATION AND SAFETY

8:43A-17.1 Housekeeping policies and procedures

(a) The housekeeping service shall have written policies and procedures that are reviewed every three years or as needed, revised as needed, and implemented. They shall include, at least, scope of responsibility, assignment by designated unit, and responsibility for all cleaning tasks.

(b) The housekeeping service shall have a written schedule that determines the frequency of cleaning and maintaining cleanliness for all equipment, structures, areas, and systems within its scope of responsibility.

(c) There shall be a list available at all times of all cleaning and disinfecting agents used in the facility together with their Materials Safety Data Sheets (MSDS).

(d) Records of all pesticides and herbicides used at the facility shall be maintained on-site, together with their Materials Safety Data Sheets (MSDS).

(e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, as specified by the manufacturer, including agents that have been repackaged from a bulk source.

(f) All pesticides shall be applied in accordance with State Pesticide Control Code, N.J.A.C. 7:30.

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3538(a).
Section was "Provision of services".

8:43A-17.2 Housekeeping staff

(a) There shall be an individual responsible for the housekeeping or environmental services. This individual may be a contracted provider.

(b) Housekeeping personnel shall be trained upon hire and on an annual basis or more frequently as necessary. Training should focus on cleaning procedures, including the selection and use of appropriate chemicals in the cleaning and care of equipment and surfaces.

Repeal and New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3538(a).
Section was "Housekeeping".

8:43A-17.3 Housekeeping patient services

(a) All areas, including areas with limited access such as cabinet drawers, locked medication rooms, and storage areas, shall be kept clean to sight and touch and free of condensation, mold growth and noxious odors.

(b) All equipment and materials necessary for cleaning, disinfecting, and sterilizing (if applicable) shall be provided.

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
PO Box 367
Trenton, New Jersey 08625–0367

(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.

8:43A–19.8 Construction and renovation

(a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.

1. The infection control program shall review areas of potential risk and populations at risk. The infection control program shall approve control measures, if necessary.

(b) The design phase shall include commissioning specifications of ventilation requirements used during and at completion of the construction project.

(c) An education program shall be established for facility employees of the areas affected, the contractor's employees, and the contractor to define the impact, risks, interventions and compliance issues.

New Rule, R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).

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. 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 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–21.3 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–21.4 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.

8:43A-21.5 (Reserved)

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 professional 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. RENAL DIALYSIS

8:43A-24.1 Scope of renal dialysis standards

The standards within this subchapter shall apply to both hemodialysis and peritoneal dialysis units within ambulatory care facilities providing renal dialysis services. Ambulatory care facilities that provide chronic dialysis services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter. Hospital facilities that provide renal dialysis services within the hospital shall comply with N.J.A.C. 8:43G-30 and with the requirements of this subchapter, except as specifically modified by N.J.A.C. 8:43G-30.

8:43A-24.2 Definitions

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

"Ambulatory dialysis" means maintenance dialysis therapy provided to an individual on an outpatient basis.

"Patient care technician" means unlicensed dialysis facility staff who has been specifically trained and demonstrates competency to provide direct patient care, under the direct supervision of a registered professional nurse, to individuals receiving dialysis services.

8:43A-24.3 Minimum and maximum program size and transfer agreements

(a) A facility providing ambulatory dialysis services shall have at least six stations. In the case of new construction or renovation involving at least 25 percent of the existing physical plant, an open treatment area shall contain no more than 21 stations.

(b) A facility providing ambulatory dialysis services shall have a written transfer agreement with at least one hospital with a New Jersey license to provide inpatient dialysis and with at least one hospital having a Medicare-certified and Department-licensed renal transplantation program.

8:43A-24.4 Renal dialysis policies and procedures

(a) The renal dialysis service shall have written policies and procedures that are reviewed every three years, revised as needed, and implemented. They shall include at least:

1. Admission criteria for the ambulatory dialysis service that includes acceptance of patients who have communicable or transmittable diseases;

2. Criteria for handling the abusive or disruptive patient;

3. Orientation of new patients to the unit;

4. Specific facility response to medical and non-medical emergencies including, for example, equipment failure and water supply problems; and

5. Prohibition against patients bringing food into the unit, except for beverages which may be allowed at the discretion of the facility director.

(b) The renal dialysis service shall have written infection control policies and procedures specific to the renal dialysis unit that include standard industry precautions. The written policies and procedures shall be in accordance with the Centers for Disease Control and Prevention (CDC) publication "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," MMWR, Vol. 50, No. RR-5, April 27, 2001, as amended and supplemented, available from the CDC, Atlanta, Georgia 30333, incorporated herein by reference.

8:43A-24.5 Qualification of the medical director

The medical director of a facility that provides ambulatory 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 certified in the subspecialty of nephrology by either the American Board of Internal Medicine of the American Board of Medical Specialties or by the American Osteopathic Board of Internal Medicine, Bureau of Osteopathic Specialists of the American Osteopathic Association.

8:43A-24.6 Renal dialysis staff qualifications and policies and procedures

(a) Renal dialysis services shall be under the administrative supervision of an individual with at least one of the following qualifications:

1. A baccalaureate degree from an accredited college or university and the equivalent of at least one year experience in supervising renal dialysis services; or

2. Five years full-time experience in the provision of renal dialysis services and documentation of supervisory experience for at least one year.

(b) The medical staff shall possess the following quailfications:

1. Each physician on the medical staff shall have a current license to practice medicine in the State of New Jersey, and current Drug Enforcement Administration (DEA) and Controlled Dangerous Substances (CDS) certificates.

2. The members of the medical staff may include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients.

3. Advanced practice nurses or physician assistants shall meet the requirements established by the Board of Nursing in New Jersey (for an advanced practice nurse—N.J.A.C. 13:37-7) or the Board of Medical Examiners in New Jersey (for a physician assistant—N.J.A.C. 13:35-2B).

(c) The director of nursing services is the registered professional nurse who has overall responsibility for the provision of nursing care in the facility. The director of nursing shall have a current New Jersey license to practice nursing and shall meet the qualifications set forth in N.J.A.C. 8:43A-1.l0, except that the minimum 12 months of full-time experience in nursing supervision and/or nursing administration shall have been obtained in a hemodialysis setting within the last 24 months.

(d) Each nurse assigned charge responsibilities shall be a New Jersey-registered nurse currently licensed to practice and have 12 months of full-time experience in hemodialysis obtained within the last 24 months. The responsibilities of a registered professional nurse functioning as a charge nurse shall include:

1. Making daily patient care assignments based on patient needs;

2. Providing immediate supervision of direct patient care;

3. Making patient assessments when indicated; and

4. Communicating with the other members of the health care team.

(e) Dialysis facilities shall assign licensed practical nurses to perform nursing functions within their defined scope of practice, as set forth in the New Jersey Nurse Practice Act at N.J.S.A. 45:11-23.

(f) Patient care technicians shall be subject to the following policies and procedures:

1. Technicians shall be trained and deemed competent by the facility in accordance with facility policies and procedures in the following areas:

i. Principles of hemodialysis;

ii. Understanding the individual with kidney failure;

iii. Application of dialysis procedures;

iv. Application of dialysate, dialysers and reuse; and

v. Water treatment.

2. A competency evaluation covering the areas identified in (f)1 above shall be performed for each patient care technician and shall be included as a component of the policies and procedures.

i. Until the successful completion of each component of the competency evaluation, the trainee may provide patient care only as part of the training program and under the direct supervision of an assigned preceptor. A preceptor shall be a licensed registered nurse who has 12 months of experience in hemodialysis obtained within the last 24 months and a recommendation by the supervising nurse to be a preceptor.

ii. An individual may not work as a patient care technician unless and until that individual has satisfied the competency requirements in each of the five training areas established in (f)1 above.

3. Trainees shall be identified as such to patients in the treatment area. Trainees shall not be included in the determination of compliance with minimum staffing ratios as set forth at N.J.A.C. 8:43A-24.7(a).

4. Patient care technicians are prohibited from performing any of the following activities:

i. Comprehensive clinical assessment of the patient;

ii. Primary responsibility for patient education;

iii. Alteration of ordered treatment, including shortening of the treatment time;

iv. Administration of medications;

v. Administration of blood or blood products;

vi. Performance of non-access site arterial puncture; or

vii. Acceptance of physician orders.

(g) Registered dietitians shall possess at least one year of clinical experience as a registered dietitian.

(h) Social workers shall possess a master's degree in social work from a program accredited by the Council on Social Work Education. The facility shall designate one social worker in charge of social services.

8:43A-24.7 Dialysis staffing

(a) The qualified individual who serves as the director of nursing services, as defined in N.J.A.C. 8:43A-8.2, shall have that responsibility at only one facility.

(b) The director of nursing services may also function as facility administrator or alternate facility administrator.

1. However, if the director of nursing is functioning in an administrative capacity, this individual shall not assume patient care and/or charge nurse responsibilities.

2. In addition, under no circumstances shall any direct care personnel, including the charge nurse, perform any administrative responsibilities not directly related to the clinical care they are providing or directly supervising for the facility.

(c) At least one registered nurse shall be on duty for the first nine patients receiving dialysis services on the premises and an additional registered nurse shall be on duty for each additional nine patients, or any portion thereof.

(d) At least one registered nurse, licensed practical nurse, or trained patient care technician shall be on duty for every three patients receiving dialysis services.

(e) All registered nursing staff shall receive on-site training in renal dialysis techniques, as determined by the facility, before permitted to work independent of direct supervision of another registered nurse with 12 months experience in hemodialysis nursing.

(f) Only a registered nurse shall direct the home (self) care dialysis training program.

1. The registered nurse may elect to assign home (self) care training licensed practical nurses.

2. One licensed nurse shall be on duty for every two patients on the premises receiving home (self) care dialysis training.

(g) If self-care dialysis services are provided on the premises, there shall be a minimum of one licensed nurse on duty for every six patients on the premises receiving self-care dialysis, exclusive of personnel engaged in training.

8:43A-24.8 Infection prevention and control

(a) 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.

(b) The facility shall have written infection control policies and procedures specific to the dialysis service, which shall include standard precautions in accordance with N.J.A.C. 8:43A-24.4(b).

(c) Transducer filters shall be replaced if wetted.

(d) The facility shall maintain dialysis infection control standards as recommended in the current guidelines from:

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333.

8:43A-24.9 Reuse of dialyzers

(a) If dialyzers are reused, reuse shall conform with the guidelines in the Association for the Advancement of Medical Instrumentation (AAMI) publications, "Hemodialyzers," 2nd Edition and Amendment, RD16:1996 and A1:2002, "Hemodialyzer blood tubing," 2nd Edition and Amendment, RD17:1994 and A1:2002, and "Reuse of hemodialyzers," 3rd Edition and Amendment, RD47:2002 and A1:2003, incorporated herein by reference as amended and supplemented.

1. AAMI publication can be obtained from:

Association for the Advancement of Medical Instrumentation
Suite 602
1901 North Fort Meyer Drive
Arlington, VA 22209

(b) The facility's policy on dialyzer reuse shall be explained to all renal dialysis patients.

1. Patients who consent to reuse shall sign an informed consent form informing them of the risks associated with dialyzer reuse.

2. If the patient declines reuse, arrangements shall be made for the patient to receive single-use treatment in the unit.

(c) Reuse of bloodlines and transducer filters is prohibited with the exception of home dialysis equipment that is for the use of a single dialysis patient and is specifically designed by the manufacture to permit the reuse of bloodlines.

(d) Water used in dialyzer reprocessing systems shall be analyzed for endotoxins from the water source outlets at least monthly and more often as necessary.

(e) In the case of centralized reuse processing, the facility is responsible for the quality of the reuse dialyzer and performance standards.

8:43A-24.10 Water treatment and dialysate

(a) Water treatment equipment, water and dialysate shall satisfy the requirements specified in the Association for the Advancement of Medical Instrumentation (AAMI) publications entitled, "Water treatment, equipment for hemodialysis applications," RD62:2001, "Dialysate for hemodialysis," 1st Edition, RD52:2004, "Hemodialysis systems," 3rd Edition, RD5:2003, and "Concentrates for hemodialysis," RD61:2000, as amended and supplemented, incorporated herein by reference.

1. Samples shall be taken at the first and last station and at least 10 percent of the stations on a rotating basis within the distribution system to insure each station is tested semi-annually. A calibrated loop may not be used in microbiological testing of water samples.

2. Water and dialysate samples shall be microbiologically analyzed at least monthly. Water samples shall be taken immediately beyond the last water treatment device and at other locations in each treatment area so as to ensure that water throughout the distribution lines conforms with AAMI standards.

i. The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect

the quality of the product water as measured by this device shall be located after the sensing cell.

ii. Chemical analysis of the water shall be performed every six months and following any change in the water system which may cause a degradation of the water quality.

3. The chlorine and chloramine testing shall be done at the start of daily operations and at times no greater than four-hour intervals daily.

4. Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series appropriately used.

5. Preparation of dialysate onsite requires the facility to establish policies and procedures to assure the safety and efficacy of the dialysate solution. A record of preparation of the dialysate shall be maintained.

6. Water supply systems shall be designed to supply water to the fixtures and equipment at a minimum pressure recommended by the manufacturer during periods when fixtures and equipment are in use.

7. The facility shall have written policies outlining the training, responsibilities, and competencies of staff responsible for maintaining water treatment processing.

8. Written records of analysis procedures and results and of equipment maintenance shall be maintained in the facility daily. Written records of daily analysis procedure results shall be maintained. Daily logs shall include the acceptable parameters for the processes being monitored.

9. Each facility shall maintain records documenting staff responsible for water procedures and monitoring.

8:43A-24.11 Supplies and equipment

(a) Every facility shall have at least one operational back-up machine for the first six machines. For each additional 10 machines, an additional operational back-up machine is required.

(b) All equipment that is present in the facility shall be functional and maintained in operational condition and in sufficient numbers to adequately service all patients.

(c) The facility shall follow all procedures and processes as required or recommended by the manufacturer of the dialysis equipment being used in the treatment of patients.

(d) Patients shall be dialyzed in chairs that can be adjusted so that the patient's head is lower than his or her feet, except when the patient is dialyzed in a hospital bed or stretcher.

8:43A-24.12 Renal dialysis staff education and training

(a) Each facility shall develop, revise as necessary, and implement a written plan of staff education. The plan shall address the educational needs, relevant to the renal dialysis service, of different categories of staff on all work shifts. The plan shall include education programs conducted at least annually.

(b) The staff education plan shall include education programs that address at least the following:

1. Orientation of all staff to the facility or service in which the individual will be employed including a review of the service's equipment, policies, and procedures and identification of individual employee duties for receiving and evacuating patients in the event of a disaster;

2. Use of new clinical procedures, new equipment, and new technologies, including where applicable, computers;

3. Individual staff requests for education programs;

4. Educational needs based on assessment of staff performance and competency;

5. Facilities shall establish a process for evaluation of staff competencies, which shall be performed and documented at least annually;

6. Areas identified by the facility quality assurance program as needing additional educational programs; and

7. Rights and responsibilities of staff under the New Jersey Advance Directives for Health Care Act (N.J.S.A. 26:2H-53) and the Federal Patient Self Determination Act (42 U.S.C. §1395cc(f)) and internal facility policies and procedures to implement these laws.

(c) Facilities shall maintain a record of attendance for each educational program offered and composite records of inservice participation for each staff member.

8:43A-24.13 Patient care plan

(a) The referring or transferring facility shall provide the receiving facility the most recent patient care plan, copies of summaries of the patient's treatments, records, medical progress, a description of dietary care, a summary of the patient's current needs and results of laboratory tests prior to transfer.

(b) Within one calendar month of initiation of dialysis treatment at the facility, a written plan of care shall be developed for each ambulatory dialysis patient by a multidisciplinary team consisting of at least, a nephrologist, a transplant surgeon or designee, a registered professional nurse, a dietitian, and a licensed social worker. The plan of care shall specify observable and measurable goals and expected patient outcomes. The multidisciplinary team shall analyze patient outcomes on a regular basis to assess the patient's progress and evaluate current and future treatment modalities and modify the plan as necessary.

(c) Every six months at minimum, the multidisciplinary team shall discuss and review the written patient care plan with each ambulatory dialysis patient and/or family, and shall revise as needed.

(d) Each member of the multidisciplinary team shall enter progress notes into the chronic dialysis patient's medical record. Progress notes by the physician, registered professional nurse and dietitian shall be entered in the patient's medical record at least monthly and by the social worker at least quarterly.

8:43A-24.14 Medical records

(a) In addition to compliance with the requirements of N.J.A.C. 8:43A-13, the facility shall assure the following:

1. An area for medical records storage, which is separate from all patient treatment areas, shall be provided. The medical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (that is, microfilm or optical disc), the medical records area shall have adequate space for transcribing records in electronic format. The facility shall store the active medical record of each patient currently treated by the facility on site.

2. Signature stamps are not used to authenticate medical record entries.

3. Each medical record shall include:

i. A problem list, including access surgeries for dialysis and prior hospitalizations;

ii. A transfusion record;

iii. A record of creation and revision of access for dialysis; and

iv. Evidence of patient education.

4. A patient's medical history and physical examination shall be completed within 30 days before or two weeks after initial treatment at the facility. For physical examinations performed prior to admission to the renal facility, the admitting physician, nurse practitioner, or physician assistant shall review the physical examination findings prior to the patient's first treatment at the renal dialysis facility and shall indicate on the physical exam form any significant changes in the patient's medical condition that occurred since the physical examination was performed.

i. Prior to the first treatment in the facility, the physician shall inform the nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data. No dialysis shall be initiated until this requirement is met.

5. Prior to providing dialysis treatment of a transient patient, a facility shall obtain and include, at a minimum:

i. Orders for treatment in the facility;

ii. A list of the patient's current medications and any known patient allergies;

iii. Laboratory reports performed no later than one month prior to treatment at the facility, including screening for hepatitis B status;

iv. The most current patient care plan; and

v. The most current treatment records from the referring facility.

6. At the completion of treatment at the transient facility, records of care and treatment are provided to the referring facility.

8:43A-24.15 Physical plant requirements for all ambulatory dialysis facilities

(a) Each station in the ambulatory dialysis service shall have a curtain for privacy. One handwashing sink shall be available for every four stations. These handwashing sinks shall be distributed throughout the treatment area so as to ensure immediate accessibility to staff at all times.

(b) The minimum dimensional requirements for each dialysis station shall be:

1. There shall be a minimum width of 10 feet along the service wall.

2. The floor area within the cubicle curtain of each dialysis station shall be at least 80 square feet and shall not include the area of the service wall.

3. There shall be 30 inches of clear space around each machine and lounge, except that one side of the machine may be installed flush against the wall.

4. There shall be a minimum of four feet between beds and/or lounges.

5. The dimensional requirements listed in (b)1 through 4 above shall apply to those facilities initially licensed March 6, 2006 or later.

6. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in (b)1 through 4 above.

(c) The floor of the dialysis treatment area, reuse rooms, soiled utility rooms, and any areas used for mixture of dialysate shall be monolithic with integral base.

(d) There shall be a separate clean holding area or room within the ambulatory dialysis suite for storage of clean supplies.

1. If the facility has a clean utility room, then the clean utility room shall contain a minimum of 120 square feet and handwashing facilities.

8:43A-25.4 Physical plant; computerized tomography and magnetic resonance imaging services

A new ambulatory care facility which provides computerized tomography or magnetic resonance imaging services shall comply with Chapter 9, Section 9.1, and Chapter 7, Section 7.10 and 7.11, of the Guidelines for Construction and Equipment of Hospitals and Medical Facilities, 1987 edition, as amended, incorporated herein by reference. Existing facilities shall be in compliance with these standards or the corresponding standards in effect at the time of construction, alteration, or approval.

8:43A-25.5 Physical plant; radiological services

(a) If radiological services are provided in a freestanding facility, the suite shall contain the following:

1. A radiographic room(s), which, if computerized tomography or magnetic resonance imaging services are provided, shall have an area of at least 250 square feet;

2. A film processing room;

3. A viewing area;

4. Film storage facilities for active, inactive, and unexposed film;

5. Office space for medical staff and administrative functions;

6. A waiting area for ambulatory patients and patients requiring wheelchairs or stretchers;

7. A dressing area(s) with convenient access to public toilets;

8. A toilet room(s) with handwashing facilities for staff, visitors, and patients;

9. Handwashing facilities, which shall be available to each procedure room;

10. A control desk and reception area;

11. Storage facilities, including at least the following:

i. A room or closet for storage of the clean linen supply; and

ii. A room for storage of soiled linen; and

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

SUBCHAPTER 26. DRUG ABUSE TREATMENT SERVICES

8:43A–26.1 Additional requirements and exceptions

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

1. An ambulatory care facility which provides only drug abuse treatment services need not comply with N.J.A.C. 8:43A–6.9 and 8.2 for the purpose of licensure.

8:43A–26.2 Smoking in facility

(a) The facility shall become smoke-free within three months of the effective date of this section. "Smoke-free" means a total ban on smoking in the facility by employees and visitors. Prior to the time at which the facility becomes smoke-free, the policy of the facility regarding smoking in the facility shall be in accordance with N.J.S.A. 26:3D–1 et seq.

1. If the facility permits patients to smoke after the facility becomes smoke-free, smoking by patients shall only be permitted in accordance with N.J.S.A. 26:3D–1 et seq. and in a designated area with outside ventilation. The ventilation system shall prevent contaminated air from recirculating through the facility and shall prevent backstreaming of smoke into nonsmoking areas of the facility.

8:43A–26.3 Additional services

A facility providing drug abuse treatment services shall provide, or arrange provision of, educational services, vocational counseling and training, and job placement to patients whose plans of care indicate a need for such services. In the case of patients who require legal services, the facility shall refer the patient to an agency providing legal services.

8:43A–26.4 Nurse staffing

(a) Ambulatory care facilities which provide drug abuse treatment services shall designate in writing a registered professional nurse as the director of nursing services. The director of nursing services, or a registered professional nurse designated in writing to act in the absence of the director of nursing services, shall be on the premises of the facility whenever medications are being administered and at times specified by the facility in the policy and procedure manual.

1. If the policies and procedures of the facility ensure that the conditions below are satisfied, then the facility need not comply with (a) above or with N.J.A.C. 8:43A–8.1:

i. Medications, including methadone, shall not be dispensed or administered in the facility;

ii. For each patient, the drug counselor to whom the patient is assigned shall obtain health-related information from the patient using a protocol or form approved by the medical director and shall record the information in the patient medical record. If the drug counselor determines that there is a need for immediate intervention by a physician or nurse, the counselor shall immediately notify the medical director or registered professional nurse or shall immediately provide the patient with an appropriate referral; and

iii. A physician or a registered professional nurse shall review each patient's health-related information within 15 days of the interview of the patient by the drug counselor. The physician or registered professional nurse shall determine the need for direct assessment by a physician or registered professional nurse or for referral to another health care provider. Direct assessment shall be ordered or referral made on the basis of this determination.

(b) In facilities providing methadone detoxification or methadone maintenance services, there shall be at least one registered professional nurse present in the facility for 150 or fewer patients and at least one additional licensed nurse present in the facility for each additional 150 or fewer

patients, during all hours when medications are administered.

8:43A–26.5 Drug abuse counseling services

(a) If the facility provides drug abuse treatment services, drug abuse counseling services shall be provided directly in the facility to patients.

(b) A facility providing drug abuse treatment services shall, in addition to complying with N.J.A.C. 8:43A–10, comply with the following:

1. Each patient shall be assigned to a drug counselor, with assignment documented in the patient's medical record. A drug counselor's caseload shall not exceed 50 patients;

2. All outpatient methadone detoxification programs shall provide a minimum of one counseling session per week to each patient during the first four months after initiation of treatment and at least one counseling session every two weeks thereafter until discharged;

3. All outpatient methadone maintenance programs shall assign each patient to one of the following stages and provide counseling to the patient in accordance with the following schedule:

i. Stage I. At least one counseling session per week during the first three months of treatment;

ii. Stage ii. At least one counseling session every two weeks from the beginning of the fourth month to the end of the ninth month of treatment;

iii. Stage Iii. At least one counseling session per month from the beginning of the tenth month to the end of the second year of treatment; and

iv. Stage IV. At least one counseling session every three months after completion of two years of treatment;

4. A patient in an outpatient methadone maintenance program who becomes symptomatic of drug or alcohol abuse for the first time after admission shall return to a minimum of one counseling session per week until symptoms cease and shall remain in his or her present stage of treatment;

5. A patient in an outpatient methadone maintenance program who becomes symptomatic of drug or alcohol abuse for a second or subsequent time after admission may be returned to a lower stage of treatment; and

6. Drug abuse counseling services shall include the provision of individual counseling and the availability of group, family, and/or vocational counseling.

(c) If an administrator performs both administrative and other functions, written documentation of the administrator's time spent in each function shall be maintained. The administrator's time spent in administrative functions shall not be included in the computation of staffing levels for nursing or counseling services.

8:43A–26.6 Designation of consultant pharmacist

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

8:43A–26.7 Medical records

The complete medical record for patients receiving drug abuse treatment services shall include, but not be limited to, a copy of the Alcohol and Drug Abuse Data System (ADADS) form (See Appendix A) or other management information system form approved by the Division of Alcoholism, Drug Abuse and Addiction Services of the Department, incorporated herein by reference.

8:43A–26.8 Notices

The hours of operation and the business telephone number of the facility shall be posted so as to be visible from the outside of the main entrance of the facility.

8:43A–26.9 Employee health

The Mantoux tuberculin skin test required by N.J.A.C. 8:43A–3.7(d) shall be repeated on an annual basis for all employees.

SUBCHAPTER 27. SATELLITES OF LICENSED AMBULATORY CARE FACILITIES

8:43A–27.1 Additional requirements and exceptions

(a) A satellite of a licensed ambulatory care facility, 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 satellite also provides surgical or anesthesia services, then the satellite shall also comply with N.J.A.C. 8:43A–12.

1. A satellite of a licensed ambulatory care facility need not comply with N.J.A.C. 8:43A–2.4(c), 5.1, 6.3(b) and 13.1(c) for the purpose of licensure.

(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 documented 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 Scope

(a) All lithotripsy providers shall be licensed by the Department of Health and Senior Services and shall comply with the rules in this subchapter and all applicable requirements of this chapter, as well as all applicable requirements in N.J.A.C. 8:43A–1 through 19.

(b) When lithotripsy services are provided at a fixed site, that site must be separately licensed as a health care facility and meet the requirements of this subchapter.

1. In the event the fixed site is operated by a licensed general hospital, the lithotripsy services may be included on the hospital's license in accordance with this subchapter, or as a freestanding ambulatory care facility in accordance with N.J.A.C. 8:43G–2.11 and this subchapter.

2. If the licensed healthcare facility contracts with a mobile lithotripter provider, the mobile provider shall be licensed and comply with all applicable requirements of this chapter.

(c) When lithotripsy services are provided utilizing a mobile or transportable lithotripter, those services shall be provided by a licensed health care facility at the site of a licensed health care facility. The entity billing for the service shall be the licensed operator. In the event the licensee is a mobile or transportable provider, all mobile units and/or transportable lithotripters shall be individually inspected and approved by the Department. Serial numbers for mobile and transportable equipment shall be provided to the Department.

(d) The rules in this subchapter apply to all lithotripsy services and shall be enforced as a condition of licensure by the Department of Health and Senior Services.

8:43A–29.2 Purpose

The goal of this subchapter is to protect the health, safety and welfare of patients who receive lithotripsy services by establishing minimum rules and standards of care in order to be licensed to operate in New Jersey. These rules shall supplement all other applicable rules in this chapter or any other chapters that apply to a licensed health care facility (for example, hospitals, nursing homes, etc.). The rules in this subchapter, therefore, shall supercede any inconsistent rule contained in another generally applicable chapter.

8:43A–29.3 Definitions

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

"ALS" means American Lithotripsy Society. The American Lithotripsy Society is a voluntary membership organization dedicated to addressing all issues regarding the management and treatment of stone disease including aspects of lithotripsy as a treatment modality for urinary stone disease.

"Clinical privileges" means authorization granted by the appropriate authority (for example, a governing body) to a clinical practitioner to provide specific patient care services in an organization within well-defined limits, based on the following factors, as applicable:

1. License;

2. Education;

3. Training;

4. Experience; and

5. Competence, that is, the ability to perform the medical procedure and exercise sound medical judgment.

"Credentialing" means the process of obtaining, verifying and assessing the qualifications of a clinical practitioner to provide patient care services in or for a licensed health care facility.

"ESWL" as used in this subchapter stands for extracorporeal shock wave lithotripsy (ESWL) or lithotripsy, which means the process by which kidney stones are pulverized into particles of sand.

"Fixed lithotripter" means equipment that is permanently located in a designated area where patients are treated within a licensed health care facility.

"Lithotripsy services" means extracorporeal shockwave lithotripsy services, and ancillary urological and radiological services.

"Lithotripter" means equipment that is used to pulverize kidney stones into particles of sand. This equipment may be fixed, mobile or transportable.

"Mobile lithotripter" means equipment that is used to pulverize kidney stones into particles of sand and is also self-contained in a vehicle where patients are treated.

"Recovery room" means the area provided with equipment and nurses needed to care for patients who have received anesthesia. Patients remain in the recovery room until they regain consciousness and are no longer drowsy and stuporous from the effects of anesthesia.

"Transportable lithotripter" means equipment that is used to pulverize kidney stones into particles of sand and is also moved from site to site in a vehicle to a licensed health care facility. Services shall be provided in the site of the licensed health care facility.

8:43A–29.4 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 health care facility.

8:43A–29.5 Qualifications of radiologic technologists

Each radiologic technologist shall be licensed by the New Jersey State Department of Environmental Protection and shall be certified by the American Lithotripsy Society within one year of employment.

8:43A–29.6 Qualifications of urologists

(a) Each urologist shall be licensed by the New Jersey State Board of Medical Examiners to practice medicine in the State of New Jersey and shall be board certified or board eligible in his or her specialty. It shall also be deemed acceptable to possess board certification from a foreign Board within his or her specialty where the American Board of Medical Examiners offers reciprocity with or officially recognizes the foreign board-certification credential.

(b) Proof of training to perform ESWL services shall be provided a certificate or letter from the director of his or her residency program shall be accepted.

(c) The urologist shall perform the ESWL procedure.

8:43A–29.7 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–29.8 Provision of anesthesia services

(a) Anesthesia services shall be available and provided in accordance with N.J.A.C. 8:43A–12.

(b) Anesthesia services shall be provided by an anesthesiologist or by a certified registered nurse anesthetist.

8:43A–29.9 Policies and procedures

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

1. Delineation of the lithotripsy services which may be performed;

2. Delineation of the responsibilities of urologists in providing care to patients;

3. Identifying the staff qualified to participate in the provision of lithotripsy services;

4. Developing and implementing operational policies addressing at least the following concerns:

i. The maximum number of shocks and/or voltage allowable or their equivalent;

ii. Bilateral treatment;

iii. Treatment of females of childbearing age;

iv. Patient weight limitations;

v. Treatment of patients with pacemakers;

vi. Post ESWL follow-up care;

vii. Contraindicated medications;

viii. Pre-admission testing requirements;

ix. Patient outcomes;

x. Pre-and post-procedure calls to the patient;

xi. Pediatric cases;

xii. Treatment criteria;

xiii. Cancellation criteria;

xiv. Retreatment criteria;

xv. General safety protocols; and

xvi. Treatment simulation;

5. Lithotripters shall be inspected at least quarterly by a qualified person in accordance with policies and procedures approved by the urologist, all preventive maintenance shall be documented, and a service contract shall be maintained on the lithotripter according to manufacturer specifications;

6. All lithotripters shall be operated by qualified and competent personnel in accordance with facility policies and procedures approved by the urologist;

7. Policies for cleaning equipment before and after use shall be maintained and followed, including procedures for properly covering mobile or transportable equipment upon delivery;

8. Protocols to ensure that procedures are performed only after completion and documentation of appropriate history and physical examination, any indicated diagnostic tests, and the pre-procedure diagnosis;

9. Assurance that every patient is examined by a urologist immediately prior to the procedure; and

10. Requirements for written documentation of all lithotripsy services provided at the facility, including at least a description of the fragmentation, procedures, stones removed, patient's condition, any unusual events occurring during the procedure, post-procedure diagnosis, and names of the urologist and clinical staff. The procedure note shall be written or dictated immediately following the procedure by the urologist performing the procedure and incorporated into the patient's medical record.

8:43A–29.10 Education of patients and family

(a) The facility shall establish policies for the education of patients and families concerning lithotripsy services. These policies shall include efforts to improve patient outcomes by promoting healthy behavior and involving the patient and, as appropriate, family in care and care decisions. The licensee shall specify in its policies and procedures that:

1. Patient education shall be interactive and interdisciplinary;

2. Patients' learning needs and abilities shall be assessed;

3. Education activities and resources are planned and coordinated;

4. Information provided orally shall be documented in the medical record;

5. Printed and/or written instructions and information for patients, with multilingual instructions as required, shall be provided. Information shall include tests and/or procedures needed, possible complications, a telephone number to call when needed, and instructions for obtaining care in an emergency;

6. Patients and families shall receive information about proposed care during the treatment entry process; and

7. The educational systems used and outcomes shall be evaluated as part of the performance improvement process.

8:43A–29.11 Equipment and supplies

The licensee shall provide equipment and supplies which are appropriate to the treatment needs of lithotripsy patients for the types and ages served by the licensee.

8:43A–29.12 Financial arrangements

Licensees shall comply with all applicable requirements of this chapter concerning financial arrangements, and additionally all licensees and all facilities approved to perform lithotripsy services shall provide care to all patients who medically require lithotripsy services, regardless of the patient's ability to pay.

8:43A–29.13 Data collection and reporting for performance improvement

(a) In addition to the requirements of N.J.A.C. 8:43A–18, licensees shall maintain the following information necessary for outcomes data collection:

1. The number of treatments provided at the facility;

2. The number of mortalities; and

3. Patients discharged for in-patient admission directly from outpatient lithotripsy treatment.

(b) The data identified in (a) above shall be filed with the Department on a quarterly basis, within 30 days of the close of each calendar quarter.

(c) Licensees shall report to the Department by telephone at (609) 588–7725 or at (609) 392–2020 after hours incidents in which a medical device is connected with the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990, 21 U.S.C. § 360.

8:43A–29.14 Provision of mobile or transportable services by licensed facility

(a) A licensed lithotripsy provider that uses a mobile or transportable lithotripter shall submit an amended license application and shall not provide service using the mobile or transportable lithotripter until the application is approved.

1. The licensed health care facility where the mobile or transportable lithotripsy services will be provided shall be inspected prior to the provision of those services to ensure that all applicable requirements of this chapter and subchapter are met by the licensed health care facility, the licensed lithotripsy provider, or a combination thereof.

(b) A fixed-site licensed lithotripsy facility, seeking licensure of mobile or transportable equipment, shall file an amended licensing application with the Department and provide documentation of the following:

1. The mobile or transportable services provided by the licensee's fixed site licensed lithotripsy facility is integrated with, subordinate to and accountable to the fixed lithotripsy facility in accordance with N.J.A.C. 8:43G–2.11. Where N.J.A.C. 8:43G–2.11 uses the term "hospital" or "hospital-based," that term shall mean the fixed-site licensed lithotripsy facility for purposes of this subchapter;

2. The fixed site licensed lithotripsy facility has written policies and procedures applicable to the mobile or transportable services assuring that the requirements of this subchapter are followed; and

3. The mobile or transportable lithotripter shall not be utilized prior to obtaining specific licensure by the Department. The general facility license shall not be sufficient. Every lithotripter shall be inspected and approved for licensure by the Department, prior to use.

8:43A–29.15 Physical plant; lithotripsy services

The lithotripsy suite of any facility which provides ESWL services shall conform with Chapter 9.1 B through H, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities (The American Institute of Architects Press, 1996–1997 edition, 1735 New York Avenue, N.W., Washington, D.C. 20006) incorporated herein by reference, as amended and supplemented, all applicable equipment manufacturer specifications and shall also satisfy all applicable requirements of this subchapter.

SUBCHAPTER 30. RADIATION ONCOLOGY

8:43A–30.1 Radiation oncology policies and procedures

(a) The radiation oncology service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies and procedures shall include at least:

1. Safety practices;
2. Emergencies;
3. Adverse reactions;
4. Management of the critically ill patient; and
5. Infection control.

(b) The radiation oncology facility's policies and procedures manual shall be available to staff.

(c) There shall be a written protocol for managing emergencies in the radiation oncology suite. All staff shall be instructed in this protocol and know their roles in the case of such an emergency.

(d) The facility shall have written policies and procedures to assure that the psychosocial needs of radiation oncology patients and their families are met.

8:43A–30.2 Radiology oncology continuous quality improvement methods

There shall be a program of continuous quality improvement for radiation oncology which includes regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

8:43A–30.3 Radiation therapy oncology services staff qualifications

(a) All physicians performing radiation oncology services shall have successfully completed an approved residency training program in radiology or radiation oncology.

(b) In order to be qualified under this subchapter, a radiation oncologist shall be certified by the American Board of Radiology in general radiology, radiation oncology or therapeutic radiology prior to 1976; or certified by the American Board or the American Osteopathic Board of Radiology in radiation oncology since 1976 or actively engaged in the process for certification by the American Board or the American Osteopathic Board of Radiology.

1. All radiation oncologists shall be board certified by the American Board or the American Osteopathic Board of Radiology within five years of the initial application for board certification.

2. Upon application made to the Department by the physician, a waiver of the requirement of board certification shall be granted to a radiation oncologist who is

licensed by and in good standing with the New Jersey Board of Medical Examiners as of September 18, 2000. If granted, the waiver shall remain for the duration of the applicant's career unless the applicant fails to maintain his or her status of good standing with the New Jersey Board of Medical Examiners. Should the applicant fall out of good standing with that Board, the waiver shall automatically become null and void. Physicians falling out of good standing, and subsequently achieving good standing status, shall be eligible to reapply for a subsequent waiver, provided the applicant shall show cause why a subsequent waiver should be approved.

(c) All radiation therapists in the radiation oncology facility shall be licensed by the State of New Jersey in accordance with N.J.S.A. 26:2D–24 et seq. and N.J.A.C. 7:28–19.

(d) All radiological physicists in the radiation oncology facility shall be qualified to insure that Cobalt-60 units and other energy units are calibrated and used properly.

1. For the purposes of this subchapter, qualified radiological physicists shall mean one who:

i. Is certified, or in the process of certification, by the American Board of Radiology in either radiologic physics or therapeutic radiologic physics or by the American Board of Medical Physics in radiation oncology physics; or

ii. Does not meet the criteria in (d)1i above, but whose petition for recognition as a 'qualified radiological physicist,' as defined under N.J.A.C. 7:28–14.2, has been granted by the Commission on Radiation Protection. To obtain recognition the individual shall submit a written petition to the Commission on Radiation Protection, 100 Riverview Plaza, Trenton, New Jersey 08625 which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified radiological physicist.

8:43A–30.4 Radiation oncology services staff time and availability

(a) During regular hours, a radiation oncologist shall be physically on site, including the radiation oncology facility or radiation oncology facility campus, when patients are receiving radiation treatments, except for routine absences of a short duration or for brief unexpected absences. Such absences shall not constitute more than 10 percent of the time that patients are under treatment.

(b) After the radiation oncology facility is closed, a radiation oncologist shall be on call until the facility opens again. The on-call radiation oncologist shall provide telephone consultation within one hour of being summoned and be physically present and available to evaluate and treat the patient within four hours of being summoned for radiation oncologic emergencies.

(c) There shall be at least one licensed radiation therapist or radiation oncologist present to operate each megavoltage unit when it is in use.

(d) There shall be at least two radiation therapists present to operate each linear accelerator when it is in use except under emergency conditions. A radiation oncologist may act as a substitute for one of the two therapists.

(e) A radiation physicist shall be available to the radiation oncology service on a full-or part-time basis. Multiple unit programs shall have a minimum of one full-time equivalent physicist on site. A radiation physicist must supervise all treatment calculations other than emergencies.

(f) A registered professional nurse shall be available on-site on a full-or part-time basis to the radiation oncology facility. In the case of multiple megavoltage radiation oncology unit programs, a minimum of one full-time equivalent registered professional nurse is required.

(g) The facility shall have in place a referral agreement with a social service agency to meet the psychosocial needs of the patient.

8:43A–30.5 Radiation oncology patient services

(a) A written plan of care shall be developed by the radiation oncologist upon initiation of treatment for each radiation oncology patient.

(b) Individual patient records of radiation oncology treatment shall be maintained for at least two years after the death of the patient. If no date of death is known, records shall be maintained at least until the patient would have attained the age of 90 years, or for five years, whichever is later. A copy of the record of radiation oncology treatments shall be included in the patient's medical record, if applicable.

(c) Computerized treatment planning for radiation oncology shall be available either on-site or by arrangement with another provider of services.

(d) Each patient's record shall be reviewed at least once each week to assess compliance with the plan developed by a radiation oncologist. The review shall be conducted by a physicist, chief technologist, or dosimetrist. At least one verification image shall be made prior to the initial treatment and then every two weeks thereafter for each site of disease under treatment.

(e) During a course of treatment, there shall be at least a weekly evaluation of the patient by a radiation oncologist.

8:43A–30.6 Radiation oncology services supplies and equipment

(a) Each radiation oncology facility shall have at least one dedicated fluoroscopic or computerized tomography simulator.

(b) Cobalt-60 equipment shall have a source distance of greater than or equal to 80 centimeters.

(c) All new single unit facilities shall have dual photon energy equipment with electron capability. All existing single unit facilities shall obtain dual photon energy equipment with electron capability by September 18, 2003.

(d) By September 18, 2003, new or replacement machines shall, at a minimum, provide greater than or equal to 10 MV photon energy level capability and greater than or equal to 10MeV electron energy level capability unless another machine already exists at that facility with these capabilities.

(e) By September 18, 2003, all Cobalt-60 machines shall be replaced with machines meeting the specifications outlined in (c) and (d) above.

8:43A–30.7 Radiation oncology services quality improvement methods

(a) There shall be a program of quality improvement for radiation oncology services that is integrated into the radiation oncology facility quality improvement program and includes regularly collecting and analyzing data to help identify health-service problems and their extent, recommending, implementing and monitoring corrective actions on the basis of these data.

(b) New or existing radiation oncology facilities shall be fully accredited by the American College of Radiology or the American College of Radiation Oncology by September 18, 2003 and maintained thereafter.

(c) Copies of American College of Radiology or the American College of Radiation Oncology accreditation certificate shall be sent to the New Jersey Department of Health and Senior Services as part of State licensure within 45 days of receiving the certificate.

8:43A–30.8 Megavoltage radiation oncology program utilization

(a) For existing facilities or programs, the minimum annual megavoltage radiation oncology treatment volume shall be 150 new patients per facility. A new patient is defined as one who has never before received radiation oncology treatment or a returning patient with a second primary cancer at a different site which has not been previously treated. For new facilities or programs, by the second year of operation, the minimum annual megavoltage radiation oncology treatment volume shall be 150 new patients per facility averaged over a two year period.

(b) For those facilities offering brachytherapy, the minimum annual brachytherapy treatment volume shall be an average of 10 patients per year, over a two year period.

(c) Megavoltage radiation oncology facilities providing potentially curative treatment to children under 13 years of age shall be accredited for participation in protocols of a national multi-institutional pediatric oncology group such as Children's Cancer Group (CCG) or Pediatric Oncology Group (POG).

8:43A–30.9 Independent verification of radiation oncology equipment calibration

(a) Independent verification of megavoltage radiation oncology equipment output shall be made by an external accrediting organization such as the Radiation Physics Center or MD Anderson or any other external accrediting organization approved by the Department prior to the initiation of the megavoltage service, if new, and annually thereafter.

(b) Existing megavoltage radiation oncology services shall have until September 18, 2001 to achieve initial independent verification of its MRO equipment output and shall maintain that verification annually thereafter.

8:43A–30.10 Data to be maintained and reported

Megavoltage radiation oncology facilities shall submit such utilization, performance and outcome data as the Department may request. Data shall include, but not be limited to, staff qualifications, verification of equipment calibration, program accreditation status and program utilization by service category, on reporting forms developed and annually submitted to the Department of Health and Senior Services on or before March 31.

SUBCHAPTER 31. WATER SUPPLY AND LAUNDRY

Authority

N.J.S.A. 26:2H–1 et seq.

Source and Effective Date

R.2004 d.299, effective August 2, 2004.
See: 35 N.J.R. 2838(a), 36 N.J.R. 3529(a).

8:43A–31.1 Water supply

(a) The water supply used for drinking or culinary purposes shall be adequate in quantity, of a safe and sanitary quality, and from a water system which shall be constructed, protected, operated, and maintained in conformance with

the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A–1 et seq., N.J.A.C. 7:10, and local laws, ordinances, and regulations. There shall be no back siphonage conditions present. Copies of the Safe Drinking Water Act can be obtained from the New Jersey Department of Environmental Protection, Bureau of Potable Water, PO Box 209, Trenton, New Jersey 08625–0209.

(b) Hot running water (between 105 and 120 degrees Fahrenheit or 41 to 49 degrees Celsius) and cold running water shall be provided in patient care areas.

8:43A–31.2 Laundry policies and procedures

(a) The laundry service shall have written policies and procedures, which are reviewed every three years or more frequently as needed, revised as needed and implemented. The written policies and procedures shall include a policy that identifies special handling practices for soiled laundry.

(b) All used laundry shall be considered contaminated and handled according to the facility's written policies and procedures, as approved by the infection control committee.

8:43A–31.3 Laundry patient services

(a) All soiled laundry from patient care areas shall be collected and transported in a manner to prevent any leakage.

(b) Laundry carts shall be in good repair, kept clean, and identified for use with either clean linen or soiled laundry.

(c) Clean linen shall be transported in covered carts and stored in a covered or enclosed area.

(d) Bedding (sheets, pillowcases, drawsheets, and blankets) and clothing provided to staff and patients shall be clean and in good repair.

(e) Mop heads shall be washed separately from all other laundry. A wash cycle using bleach shall be used after each mop head washing, unless the washing machine is dedicated to mop heads only.

8:43A–31.4 Laundry space and environment

(a) Soiled laundry shall be stored in containers provided for it in a clean, ventilated, vermin-proof and vermin-free area, separate from other supplies. It shall be collected from the storage area regularly so that it does not overflow or accumulate beyond the capacity of the storage containers.

(b) Soiled laundry shall be stored, sorted, rinsed, and laundered only in areas specifically designated for those purposes.

(c) If a laundry chute is used, it shall be kept locked.

(d) If a laundry chute is used, it shall be maintained in good repair and cleaned, and there shall be no build-up of visible soil.

(e) Laundry chutes shall empty into an enclosed room.

(f) If the facility has an in-house laundry for the bulk of the facility's linens, it shall provide a receiving, holding, and sorting area with handwashing facilities. The walls, floor and ceiling of the area shall be kept clean and in good repair.

(g) If the facility has a limited-use, home-style laundry (for example, for laundering items such as cubicle curtains), the walls, floor, and ceiling of the area shall be kept clean and in good repair.

(h) If the facility contracts with a commercial laundry service, the facility shall have areas for sorting and receiving laundry. These areas shall be kept clean and in good repair.

(i) A written schedule shall be developed and implemented for removing lint from laundry areas on a routine basis.

(j) If the facility has an in-house laundry, the flow of ventilating air shall be from clean to soiled areas, and ventilation shall be adequate to prevent odor build-up. Soiled laundry and clean linen shall be kept separate.

8:43A–31.5 Laundry supplies and equipment

(a) The facility shall have on-site an adequate supply in good repair of sheets, pillowcases, drawsheets, blankets, towels, washcloths, and scrub suits.

(b) All facilities shall provide laundered scrub suits in the following areas: surgical suites, obstetrical surgical suites, stage one postanesthesia care units, central processing, and those areas as determined by facility policy.

(c) If the facility has an in-house laundry, an established protocol shall be followed to reduce the number of bacteria in the fabrics. Equipment and surfaces that come into contact with soiled laundry and clean linen shall be sanitized.

(d) The laundry service shall monitor and document at least the following:

1. Unsafe objects found;
2. Linen supply;
3. Stained linen; and
4. pH. A random sample of all laundry batches from all sources shall be sour tested to ensure neutralization of alkaline residues from built detergents. Sour testing is a test performed to indicate the degree of acidity or alkalinity of linens. Built detergents are a mixture of one or more alkaline detergents that contains not less than 50 percent anhydrous soap (pure soap, free from water). Fabric pH shall be maintained at 7.0 or below after souring when built detergents are used.

8:43A-31.6 Laundry staff education and training

(a) If applicable, requirements for the laundry staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) If applicable, orientation for new laundry employees shall include protocols for handling and receiving soiled laundry and clean linen.

8:43A-31.7 Laundry quality improvement methods

(a) There shall be a program of quality improvement for the laundry service that is coordinated with the facility quality improvement program and includes regularly collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. (See N.J.A.C. 8:43A-18, Quality Assurance Program).

(b) Facilities that contract with a commercial laundry service shall use quality improvement measures to ensure that the standards of N.J.A.C. 8:43A-31.2 through this section are met.

SUBCHAPTER 32. OTHER SERVICES

8:43A-32.1 General provisions

The following standards shall apply to health care services not specifically addressed in these rules. All ambulatory care facilities shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19.

8:43A-32.2 Services not described in this chapter

(a) In the case of a licensing application for a health care service for which the Department has no specific licensing standards, the Commissioner may impose additional requirements beyond the requirements contained in this chapter, in order to protect the health of the inhabitants of the State.

(b) If a licensing applicant proposes to utilize a new technology for which the Department has no specific licensing standards, then the applicant shall provide the Department with manufacturer's specifications for the equipment or technology proposed and documentation of compliance with these specifications.

8:43A-32.3 Waiver requests

If a licensing applicant believes that certain existing requirements of this chapter do not apply to the service proposed, then the applicant may request a waiver from those specific standards. Such requests shall follow the process outlined at N.J.A.C. 8:43A-2.9. Waiver forms are available at the Department's website address www.state.nj.us/health/hcsa/hcsaforms. html or from:

Director
Certificate of Need and Acute Care Licensure Program
Division of Health Care Quality and Oversight
New Jersey State Department of Health and Senior Services
PO Box 360
Trenton, New Jersey 08625–0360

SUBCHAPTER 33. PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS

8:43A-33.1 Scope

All PACE organizations as defined at 42 CFR §460.6 incorporated herein by reference, as amended and supplemented, shall be licensed by the Department of Health and Senior Services.

8:43A-33.2 Purpose

The purpose of this subchapter is to protect the health, safety and welfare of participants in a PACE organization in New Jersey and to establish PACE licensure standards by appropriately blending Federal and State physical plant and operational requirements.

8:43A-33.3 Compliance requirements

(a) All PACE organizations shall comply with the regulations of the United States Department of Health and Human Services at 42 CFR Part 460, incorporated herein by reference, as amended and supplemented.

(b) All PACE organizations shall comply with requirements for facilities providing primary care services at N.J.A.C. 8:43A-23.1(a) and 31.

8:43A-33.4 Waiver requests

(a) An applicant for licensure as a PACE organization may request a waiver of specific standards in N.J.A.C. 8:43A that may not apply to the service the applicant proposes.

(b) Waiver requests shall follow the process outlined at N.J.A.C. 8:43A-2.9.

(c) Waiver application forms are available at the Department's Forms page at http://web.doh.state.nj.us/forms or from:

Director
Office of Certificate of Need and Healthcare Facility Licensure
Division of Health Facilities Evaluation and Licensing
New Jersey Department of Health and Senior Services
PO Box 358
Trenton, NJ 08625-0358

APPENDIX A

ADM-6
Jan. 91

New Jersey State Department of Health

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 3rd 1st 3rd	3. Sex (M/F)	4. Birthdate (mmddyy)	5. In-House Case No. (optional)	6. Admission Date (mmddyy)

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?	10. Resid. Code Co. Municip	11. Post Office Zip Code
		1 [ ] Yes 2 [ ] No		

12. Living Arrangements (Check ALL that apply)

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

13. Legal Status (Check ALL that apply)

A [ ] No Legal Problem
B [ ] Case Pending (Criminal)
C [ ] Probation
D [ ] Parole
E [ ] DWI License Suspension
F [ ] Jail/Prison Inmate
G [ ] DYFS/Family Court Case
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?	21. Employment Status*	22. Referral Source*
		1 [ ] Yes 2 [ ] No		

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

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

28. Does Client Smoke Tobacco? 1 [ ] Yes 2 [ ] No
If yes, How many cigarettes per day? No. = (Packs X 20) Pipe = PP Cigar = CC

29. SPECIAL USE 5 10 15 20 25 30 35

Name of Agency | Name of Worker