



## **N.J.A.C. TITLE 8**

### **CHAPTER 43A**

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

#### AUTHORITY

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

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**Department of Health and Senior Services  
Division of Healthcare Quality & Oversight  
Certificate of Need and Acute Care Licensure Program**

**AMBULATORY CARE LICENSING STANDARDS  
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## **SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS**

### **8:43A-1.1 Scope**

(a) This chapter applies to all health care facilities that provide ambulatory care services, including, but not limited to:

1. 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; and

2. Abortion facilities, comprehensive outpatient rehabilitation facilities, and birth centers.

(b) 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.

(c) The rules in this chapter constitute the basis for the licensure of ambulatory care facilities by the Department of Health and Senior Services.

### **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.

"Addiction Professionals Certification Board of New Jersey, Inc." means the entity by that name for which the contact information is Addiction Professionals Certification

Board of New Jersey, Inc., 1200 Tices Lane, Suite 104, East Brunswick, NJ 08816  
(732) 249-1991, telefacsimile (732) 249-1559, [www.certbd.com](http://www.certbd.com).

"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 care facility assessment" means the annual assessment established by N.J.S.A. 26:2H-18.57, which applies to certain licensed health care facilities, which assessment the Department administers pursuant to N.J.A.C. 8:31A.

"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.

"American Academy of Health Care Providers in the Addictive Disorders" means the entity by that name for which the contact information is American Academy of Health Care Providers in the Addictive Disorders, 314 West Superior Street, Suite 508, Duluth, MN 55802, (218) 727-3940, telefacsimile (218) 722-0346, [www.americanacademy.org](http://www.americanacademy.org).

"American Board of Medical Physics" means the entity by that name for which the contact information is American Board of Medical Physics, 12100 Sunset Hills Road, Suite 130, Reston, VA 20190-5202, (703) 481-5001, telefacsimile (703) 435-4390, [www.acmp.org/abmp](http://www.acmp.org/abmp).

"American College of Radiation Oncology" means the entity by that name for which the contact information is American College of Radiation Oncology, 5272 River Road, Bethesda, MD 20816, (301) 718-6515, telefacsimile: (301) 656-0989, [www.acro.org](http://www.acro.org).

"American College of Radiology" means the entity by that name for which the contact information is American College of Radiology, 1891 Preston White Dr, Reston, VA 20191, (703) 648-8900, [www.acr.org](http://www.acr.org).

"American Osteopathic Board of Radiology" means the entity by that name for which the contact information is American Osteopathic Board of Radiology, 119 East Second Street, Milan, MO 63556-1331, 800-258-AOCR (2627) or (660) 265-4011, telefacsimile (660) 265-3494, <http://www.aocr.org/certification/index.asp>.

"Association for the Advancement of Medical Instrumentation" means the entity by that name for which the contact information is Association for the Advancement of Medical Instrumentation, PO Box 1211, Annapolis Junction, MD 20701-0211, (800) 877-249-8226 or 240-646-7031, telefacsimile (301) 206-9789, [www.aami.org](http://www.aami.org).

"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 Commissioner of Health and Senior Services.

"Commission on Dietetic Registration" means the entity by that name for which the contact information is Commission on Dietetic Registration, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995, (312) 899-0040 extension 5500 or toll-free (800) 877-1600 extension 5500, telefacsimile (312) 899-4772, [www.cdrnet.org](http://www.cdrnet.org).

"Commission on Radiation Protection" means the entity by that name that is in, but not of, the Department of Environmental Protection for which the contact information is Commission on Radiation Protection, PO Box 415, Trenton, NJ 08625-0415, (609) 984-5636, telefacsimile (609) 633-2210.

"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.

"Construction guidelines" means the Guidelines for Design and Construction of Health Care Facilities, 2006 edition, incorporated herein by reference, as amended and supplemented, published by the American Institute of Architects, for which the contact information is the American Institute of Architects, 1735 New York Avenue NW, Washington DC 20006-5292, (800) 242-3837 or (202) 626-7541, telefacsimile (202) 626-7519, [www.aia.org](http://www.aia.org).

"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.

"Coordinating Center for Health Information and Service" means the Coordinating Center for Health Information and Service of the Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services. This entity publishes the Morbidity and Mortality Weekly Report, for which the contact information is Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, 1600 Clifton Rd., MS E-90, Atlanta, GA 30333, (404) 498-1150, telefacsimile (404) 498-2389, [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr).

"Council on Social Work Education" means the entity by that name for which the contact information is Council on Social Work Education, 1725 Duke Street, Suite 500, Alexandria, VA 22314-3457, (703) 683-8080, telefacsimile (703) 683-8099, [www.cswe.org](http://www.cswe.org).

"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 Department of Health and Senior Services.

"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.

"Employee" means:

1. Full and part-time employees;
2. Persons a facility engages who are in direct contact with patients or who provide patient care;



3. Volunteer staff; and

4. Physicians and other clinical practitioners who are either salaried by the facility or have clinical privileges to provide medical care at the facility.

"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.

"Healthcare Plan Review Unit" means the Healthcare Plan Review Unit within the Bureau of Construction Project Review in the Division of Codes and Standards of the Department of Community Affairs, for which the contact information is Healthcare Plan Review Unit, Bureau of Construction Project Review, Division of Codes and Standards, Department of Community Affairs, PO Box 817, Trenton, NJ 08625-0817, (609) 633-8151.

"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. 8:33C.

"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.

"Office of Acute Care Assessment and Survey" means the survey and inspections unit for acute care services within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department, for which the contact information is Office of Acute Care Assessment and Survey, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358, (609) 292-9900.

"Office of Certificate of Need and Healthcare Facility Licensure" means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department, for which the contact information is Office of Certificate of Need and Healthcare Facility Licensure, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358, (609) 292-5960, website address for forms: [www.nj.gov/health/forms](http://www.nj.gov/health/forms).

"Office of the Ombudsman for the Institutionalized Elderly" means the unit of the same name within the Division of Elder Advocacy of the Department of the Public Advocate that investigates and responds to complaints of abuse, neglect and exploitation of individuals 60 years of age and older, who reside in licensed facilities within the State, both public and private, for which the contacted information is Office of the Ombudsman for the Institutionalized Elderly, Division of Elder Advocacy, Department of the Public Advocate, PO Box 852, Trenton, NJ 08625-0852, (877) 582-6995.

"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.

"Tuberculosis Program" means the Tuberculosis Program within the Communicable Disease Service of the Public Health Services Branch of the Department, for which the contact information is Tuberculosis Program, Communicable Disease Service, Public Health Services Branch, Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369, (609) 588-7522.

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

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

#### **8:43A-1.5 Qualifications of anesthesiologists**

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

Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

**8:43A-1.6 Qualifications of certified nurse midwife**

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

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

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

**8:43A-1.8 Qualifications of dentists**

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

**8:43A-1.9 Qualifications of dietitians**

Each dietitian shall be registered or eligible for registration by the Commission on Dietetic Registration).

**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 Addiction Professionals Certification Board of New Jersey, Inc.;
  2. Be certified by the American Academy of Health Care Providers in the Addictive Disorders;
  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**

(a) 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.

(b) 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.

**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)**

**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, which are available from the Office of Certificate of Need and Healthcare Facility Licensure.

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

<u>Service</u>	<u>Application</u>	<u>Renewal</u>
1. Chronic dialysis	\$4,000	\$4,000
2. Ambulatory surgery	\$4,000	\$4,000
3. Magnetic resonance imaging	\$4,000	\$4,000
4. Computerized 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	\$1,750	\$ 750
9. ESWL	\$4,000	\$ 4,000
10. Comprehensive rehabilitation	\$1,750	\$ 750
11. Drug abuse treatment	\$1,750	\$ 750
12. Primary care (principal)	\$1,750	\$ 750
13. Primary care (satellite)	\$ 875	\$ 375
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

(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,

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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 and may request the Office of Certificate of Need and Healthcare Facility Licensure to schedule an appointment to conduct a functional review of the application to review the conditions for licensure and operation, which request the Office shall grant.

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

<u>Service</u>	<u>Inspection Fee</u>
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
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. Other	\$1,000

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

(a) An ambulatory care facility shall provide neither the health care services listed at N.J.A.C. 8:43A-2.2(b) nor the other services to which N.J.A.C. 8:43A-32 applies unless the facility license indicates that the facility provides the service.

(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 identified in (a) above, the facility shall obtain the authorization of the Office of Certificate of Need and Healthcare Facility Licensure prior to providing the additional service.

1. The Department shall base authorization upon compliance with this chapter, and may be contingent upon an on-site inspection by Department representatives.

2. 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 that 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 Office of Certificate of Need and Healthcare Facility Licensure 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) Representatives of the Office of Acute Care Assessment and Survey shall conduct an on-site inspection of the construction of the physical plant 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.

#### **8:43A-2.5 Surveys and temporary license**

(a) When the written application for licensure is approved and the building is ready for occupancy, representatives of the Office of Acute Care and Survey shall conduct a

survey of the facility 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 Office of Acute Care Assessment and Survey of the Department when the deficiencies, if any, have been corrected, and the Office of Acute Care Assessment and Survey will schedule one or more resurveys of the facility prior to occupancy.

(b) The Department may issue full or temporary licensure to a facility when the following conditions are met:

1. A functional review (see N.J.A.C. 8:43A-2.2(k)) for review of the conditions for licensure and operation, unless the Department determines functional review to be unnecessary, has taken place between the Office of Certificate of Need and Healthcare Facility Licensure and representatives of the facility, during which the Department will advise the facility representatives 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 this chapter;

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 Office of Certificate of Need and Healthcare Facility Licensure.

(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.

**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).
- (g) The Department shall not renew a facility's license if the facility does not satisfy all ambulatory care facility assessments in arrears.

1. If a facility appeals an assessment in accordance with N.J.A.C. 8:31A-2.3, license renewal shall proceed if the licensee establishes an escrow account specifically dedicated to the payment of the assessment containing the amount of the unpaid assessment that is under appeal.

2. If the Department renews a license under the circumstances in (g)1 above, that license renewal shall be a conditional renewal that is conditioned upon payment of the assessment upon conclusion of the appeal (in addition to any other substantive licensure conditions the Department may require of a facility to meet other standards this chapter establishes).

**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 a license and shall be returned to the Office of Certificate of Need and Healthcare Facility Licensure 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 Office of Certificate of Need and Healthcare Facility Licensure.

(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 licensee shall disclose the ownership of the facility and the property on which it is located to the Department, shall make proof of this ownership available in the facility or at a designated location, and shall report any proposed change in ownership to the Director of the Office of Certificate of Need and Healthcare Facility Licensing in writing at least 30 days prior to the change and in conformance with requirements for Certificate of Need applications.

1. The Department shall not approve a change in ownership if the facility's ambulatory care facility assessments are in arrears, unless and until the arrears are satisfied.

2. If a facility appeals an assessment in accordance with N.J.A.C. 8:31A-2.3, a change in ownership may proceed, as long as the licensee establishes an escrow account specifically dedicated to the payment of the assessment containing the amount of the unpaid assessment that is under appeal.

3. If the Department approves a change in ownership under the circumstances in (a)2 above, the approval shall be a conditional approval that is conditioned upon payment of the assessment upon conclusion of the appeal (in addition to any other substantive licensure conditions the Department may require of a facility to meet other standards this chapter establishes).

(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) Upon the Department's request, a facility shall submit in writing any documents that this chapter requires to the Director of the Office of Certificate of Need and Healthcare Facility Licensing.

(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 086250717.

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

(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) The facility shall establish policies and procedures for the detection and control of the transmission of *Mycobacterium 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 Settings, 2005," incorporated herein by reference, as amended and supplemented, published in the Morbidity and Mortality Weekly Report, at MMWR 2005; 54 (No. RR-17) (December 30, 2005) published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>, pursuant to the

Occupational Safety and Health Act of 1970 Public Law 91-596, incorporated herein by reference as amended and supplemented.

1. For newly hired employees, the facility shall establish policies and procedures that will identify a new employee's baseline status of exposure to *Mycobacterium tuberculosis* and upon employment, the facility shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees.

i. The licensee shall administer a second Mantoux test in one to three weeks after the first Mantoux test to employees with a "negative" (less than 10 millimeters of induration or less than five millimeters of induration if the individual is immunosuppressed) result following the first Mantoux skin test.

ii. The licensee shall refer employees with a "positive" (greater than or equal to 10 millimeters of induration or greater than or equal to five millimeters of induration if the individual is immunosuppressed) result following either the first or second test for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease, which medical evaluation shall include, but not be limited to, a chest X-ray.

(1) 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. (d)1i and ii above are subject to the following 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. The facility shall establish policies and procedures for the periodic screening of employees for *Mycobacterium tuberculosis* that contain at least the following requirements:

i. The facility shall administer a Mantoux skin test to all tuberculin-negative employees at least annually;

ii. The frequency of testing shall be determined by the level of risk assigned by the facility's TB plan; and

iii. The facility shall maintain records of the results of employee Mantoux tuberculin testing.

3. Questions regarding tuberculosis control may be directed to: the Tuberculosis Program.

(e) The policy and procedure manual of the facility shall address employee safety and shall include procedures for the care of employees who become ill at the facility or who are injured at the facility.

#### **8:43A-3.8 Reportable events**

(a) The facility shall notify the Department immediately by telephone at (800) 792-9770 of any event occurring within the facility that jeopardizes the health or safety of patients or employees. Events that 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, judgment or award and shall be submitted on forms approved by the Department for that purpose.
1. 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 standards 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 complications, 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. "Smokefree" 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;
  4. Ensuring that medical staffing patterns are implemented;
  5. If the facility provides a cardiac rehabilitation program, ensuring that a physician is present in the facility at all times during the facility's hours of operation to supervise nonphysician personnel;
  6. Assisting in developing and maintaining written job descriptions for the medical staff, participating in the review of credentials and delineation of privileges of medical staff members, and assigning duties based upon education, training, competencies, and job descriptions;
  7. Participating in staff orientation and staff education activities; and
  8. Approving the contents, locations, and frequency of checking contents, including expiration dates, of emergency kits or carts, equipment, and supplies,

and assigning responsibility for these checks.

**8:43A-7.4 Medical policies and medical staff bylaws**

(a) The medical director shall be responsible for developing, implementing, and reviewing written medical policies, including medical staff bylaws, in cooperation with the medical staff. These shall be approved by the governing authority and shall include, but not be limited to, the following:

1. A plan for medical staff meetings and their documentation through minutes;
2. A mechanism for establishing and implementing procedures relating to credentials review, delineation of qualifications, medical staff appointments and reappointments, evaluation of medical care, and the granting, denial, curtailment, suspension, or revocation of medical staff privileges;
3. Specifications for verbal orders, including who may give verbal orders and who may receive them; and
4. A system for completion of entries in the patient medical record by members of the medical staff, including, but not limited to, specification of a time limit for completion of the medical record, not to exceed 30 days following the patient's last treatment or discharge. Entries shall be signed in accordance with N.J.A.C. 8:43A-13.4 and the facility's policies and procedures.

**SUBCHAPTER 8. NURSING SERVICES****8:43A-8.1 Provision of nursing services**

Nursing services, as required by this chapter, shall be provided in the facility. Nursing services shall be provided directly by the facility or through written agreement.

**8:43A-8.2 Designation of director of nursing services**

The facility shall designate in writing a registered professional nurse as the director of nursing services, who shall be on the premises of the facility during its hours of operation. A registered professional nurse shall be designated in writing to act in the absence of the director of nursing services.

**8:43A-8.3 Responsibilities of director of nursing services**

- (a) The director of nursing services shall be responsible for the direction, provision, and quality of nursing services provided to patients. The director of nursing services 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 nursing service. All nursing policies and procedures shall be reviewed at least annually;
  2. Participating in planning and budgeting for the nursing service;
  3. Coordinating and integrating the nursing service with other patient care services to provide a continuum of care for the patient;
  4. Ensuring that nursing staffing patterns are implemented;
  5. Assisting in developing and maintaining written job descriptions for nursing personnel, and assigning duties based upon education, training, competencies, and job descriptions; and
  6. Participating in staff orientation and staff education activities.

**8:43A-8.4 Responsibilities of licensed nursing personnel**

(a) Licensed nursing personnel shall provide nursing care to patients in accordance with the State of New Jersey Nursing Practice Act, N.J.S.A. 45:11-23 et seq., as interpreted by the New Jersey State Board of Nursing, and written job descriptions. Services provided shall be documented in the patient's medical record.

(b) The nursing care needs of the patient shall be assessed only by a registered professional nurse.

**8:43A-8.5 Nursing portion of the medical record**

(a) In accordance with written job descriptions and with these rules, nursing personnel shall enter the following in the patient's medical record:

1. The nursing portion of the patient plan of care, in accordance with the facility's policies and procedures;
2. Clinical notes; and
3. A record of medications administered. After each drug administration, the following shall be documented by the nurse who administered the drug: name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature of the nurse who administered the drug.

**SUBCHAPTER 9. PHARMACEUTICAL SERVICES****8:43A-9.1 Provision of pharmaceutical services through an institutional pharmacy**

(a) If the facility has an institutional pharmacy, the pharmacy shall be licensed by the New Jersey State Board of Pharmacy and shall possess a current Drug Enforcement Administration registration and a Controlled Dangerous Substance registration from the Department in accordance with the Controlled Dangerous Substances Acts.

(b) If the facility has an institutional pharmacy, the facility shall designate a pharmacist who shall be responsible for the direction, provision, and quality of pharmaceutical services. The pharmacist shall be responsible for, but not limited to, the following:

1. Together with the patient care policy committee, developing and maintaining written objectives, policies, a procedure manual, an organizational plan, and a quality assurance program for the pharmaceutical service;
2. Participating in planning and budgeting for the pharmaceutical service;
3. Coordinating and integrating the pharmaceutical service with other patient care services to provide a continuum of care for the patient; and
4. Assisting in developing and maintaining written job descriptions for pharmacy personnel, if any, and assigning duties based upon education, training, competencies, and job descriptions.

**8:43A-9.2 Scope**

N.J.A.C. 8:43A-9.3 through 9.5 shall apply to all ambulatory care facilities, regardless of whether or not the facility has an institutional pharmacy.

**8:43A-9.3 Policies and procedures**

(a) The facility shall develop and implement written policies and procedures, approved by the patient care policy committee, for the administration, control, and storage of medications. The patient care policy committee shall review the policies and procedures and document the review at least annually.

(b) The facility's policies and procedures for the administration, control, and storage of medications shall include, but not be limited to, policies and procedures for the following:

1. Documenting and reviewing adverse drug reactions and medication errors;

2. Discontinuing drug orders, including, but not limited to, the length of time drug orders may be in effect, for drugs not specifically limited as to duration of use or number of doses when ordered, including intravenous infusion solutions;
3. The control of the administration of toxic and dangerous drugs, including at least narcotics, sedatives, anticoagulants, antibiotics, oxytoxics, corticosteroid products, intravenous infusion solutions, and other drugs specified in the facility's policies and procedures;
4. The use of parenterals, if used, including the labeling of intravenous infusion solutions, such that a supplementary label is affixed to the container of any intravenous infusion solution to which drugs are added;
5. The purchase, storage, safeguarding, accountability, use, and disposition of drugs, in accordance with the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39, and the Controlled Dangerous Substances Acts and amendments thereto. Pharmaceutical services provided through written agreement shall be provided by a pharmacy licensed by the New Jersey State Board of Pharmacy. An individual patient may choose to obtain medications from a pharmacy which is not located in New Jersey;
6. The procurement, storage, use, and disposition of needles and syringes in accordance with all applicable Federal and State laws and rules, including those specified at N.J.A.C. 8:43A-14.6(b). All needles and syringes shall be kept in locked storage areas;
7. The control of drugs subject to the Controlled Dangerous Substances Acts and amendments thereto, in compliance with the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39, and all other Federal and State laws and regulations concerning procurement, storage, dispensing, administration, and disposition. Such policies and procedures shall include, but not be limited to, the following:
  - i. Provision for a verifiable record system for controlled drugs;
  - ii. Policies and procedures to be followed in the event that the inventories of controlled drugs cannot be verified or drugs are lost, contaminated, unintentionally wasted, or destroyed. A report of any such incident shall be written and signed by the persons involved and any witnesses present; and
  - iii. In all areas of the facility where drugs are dispensed, administered, or stored, procedures for the intentional wasting of controlled drugs, including the disposition of partial doses, and for documentation, including the signature of a second person who shall witness the disposition;
8. The security of the keys or codes to locked drug storage areas, including specification of the personnel who may retain the keys or security codes. Only licensed nursing or medical personnel shall retain the keys or security codes to

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storage areas in which drugs subject to the Controlled Dangerous Substances Acts and amendments thereto are kept;

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

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

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

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

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

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

#### **8:43A-9.4 Administration of medications**

- (a) All medications administered shall be prescribed in writing. Each written order shall specify the name of the drug, dose, frequency, and route of administration and shall be signed and dated by the prescriber.
- (b) Medications shall be dispensed only in accordance with prescriber orders and all Federal and State laws and rules. Medications shall be administered only in accordance with prescriber orders, medical staff policy, and all Federal and State laws and rules by licensed or authorized medical, dental, or nursing personnel.
- (c) Medications shall not be removed from their original prescription containers until the time of drug administration.
- (d) Each patient shall be identified prior to drug administration.
- (e) Drugs dispensed for one patient shall not be administered to another patient.
- (f) Drug allergies shall be documented in the patient's medical record and on its outside front cover. Other allergies shall be documented in the patient's medical record.
- (g) Medication errors and adverse drug reactions shall be reported immediately to the

nurse in charge and to the prescriber, and an entry shall be made in the patient's medical record. The incident shall be reported in accordance with procedures established by the facility. The incident shall be reported to the pharmacy, in accordance with policies and procedures approved by the patient care policy committee.

#### **8:43A-9.5 Storage of drugs**

- (a) All drugs, except intravenous infusion solutions, shall be kept in locked storage areas. Drug storage and preparation areas shall be kept locked when not in use.
- (b) All drugs shall be stored under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.
- (c) Drugs for external use shall be kept separate from drugs for internal use.
- (d) All drugs in Schedule II of the Controlled Dangerous Substances Acts and amendments thereto shall be stored in a separate, locked, permanently affixed compartment within the locked medication cabinet, medication room, refrigerator, or mobile medication cart.
- (e) A declining inventory of all drugs in Schedules I through V of the Controlled Dangerous Substances Acts and amendments thereto shall be made at the termination of each shift and shall be retained wherever these drugs are maintained.
- (f) Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source or exact identification (such as lot number), and outdated, recalled, or visibly deteriorated medications shall be returned to the institutional pharmacy for disposal. In the absence of an institutional pharmacy, such drugs shall be brought to a location specified in the facility's policies and procedures for disposal in accordance with Federal and State laws.



**SUBCHAPTER 10. COUNSELING SERVICES****8:43A-10.1 Provision of counseling services**

(a) The facility shall provide, directly or through written agreement or through a documented referral mechanism, dietary counseling and social work services. All patients who have been identified as needing, or who have requested, other counseling services such as, but not limited to, genetic, psychological, and drug abuse counseling shall be referred to appropriate providers.

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

1. The provision, direction, and method to assure the quality of counseling services provided to patients;
2. The development and implementation of written objectives, standards of practice, and an organizational plan for counseling services;
3. Coordinating and integrating the counseling services with other patient care services in the facility and with services in the community to provide a continuum of care for the patient;
4. Staff orientation and staff education programs for the counseling staff; and
5. Entering in the patient's medical record:
  - i. The counseling service elements of the patient plan of care; and
  - ii. Clinical notes.

**8:43A-10.2 Provision of social work services**

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

**8:43A-10.3 Provision of dietary counseling**

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

**SUBCHAPTER 11. LABORATORY AND RADIOLOGICAL SERVICES**

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

- (a) The facility shall provide laboratory and radiological services directly or through written agreement.
- (b) Laboratory services shall be provided only by facilities which are licensed or approved by the Department, in accordance with N.J.A.C. 8:44 and 8:45.
- (c) Radiological services shall be provided only by facilities which are registered by the New Jersey State Department of Environmental Protection, Bureau of Radiological Health, in accordance with N.J.A.C. 7:28.
- (d) The facility shall establish and implement policies and procedures for obtaining, identifying, storing, and transporting laboratory specimens.

## **SUBCHAPTER 12. SURGICAL AND ANESTHESIA SERVICES**

### **8:43A-12.1 Services**

- (a) If the facility provides surgical services to patients, the surgical and anesthesia services provided shall be limited to those procedures approved by the governing authority and the medical staff.
- (b) Surgical procedures requiring the patient to remain in the facility for more than 24 hours shall not be performed in the facility.

### **8:43A-12.2 Definitions**

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

"Advanced Cardiac Life Support" (ACLS) means that an individual has successfully completed a course of training offered by an individual who is currently certified as an instructor by the American Heart Association or by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those treating adult patients, training in ACLS is appropriate and for those treating children, training in pediatric advanced life support (PALS) is appropriate.

"Analgesia" means the absence of the sensibility to pain without loss of consciousness or decrease in the intensity of pain.

"Anesthesia" consists of general anesthesia and spinal or regional anesthesia. It does not include local anesthesia.

"Anesthesiologist" means a physician who has successfully completed an approved residency program in anesthesiology, 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.

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

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

"Certified registered nurse anesthetist" (CRNA) means a registered professional nurse who is licensed by the New Jersey State Board of Nursing and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), and who meets the conditions for practice as set forth at N.J.A.C. 13:37-13.1.

"Conscious sedation" means a drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain an open airway, and spontaneous ventilation is adequate. Adequate cardiovascular function is usually maintained. Within the context of this subchapter, "conscious sedation" shall be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.

"Deep sedation" means a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

"Epidural" means an anesthetic injected into the epidural space surrounding the fluid filled sac (the dura) around the spine which partially numbs the abdomen and legs.

"General anesthesia" means a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

"Labor analgesia" means the reduction or management of pain during labor, which involves the use of anesthetic agents and/or an epidural.

"Local Anesthesia" consists of drugs or agents which produce a transient and reversible loss of sensation in a circumscribed portion of the body.

"Major regional anesthesia" means nerve blocks such as epidural, caudal, axillary, brachial, and spinal anesthesia.

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

"Minor surgery" means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intraoperative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor

surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic surgical procedures, such as treatment of chalazions and noninvasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as "major surgery" within the meaning of N.J.A.C. 13:35-4.1.

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

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

"Pain management" means the administration of drugs to a patient, which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain occurring in the absence of an invasive, operative, or manipulative procedure.

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

"Privileges" means having been granted permission by a facility to provide specified anesthesia services, such as the administration or supervision of one or more types of anesthetic agents or procedures.

"Regional anesthesia" means the administration of anesthetic agents to interrupt nerve impulses.

"Registered nurse anesthetist" means an individual who is a qualified candidate for certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), subject to the limitations and restrictions established by the New Jersey State Board of Nursing (N.J.A.C. 13:37-13.2; Practice pending the results of the examination).

"Special procedure" means various diagnostic or therapeutic interventions which may require the administration of sedation, analgesia, or anesthesia. Examples include, but are not limited to: endoscopy, oral surgery, radiologic procedures or emergency procedures.

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

"Supervision" means responsibility by a physician who has obtained facility privileges in accordance with medical staff bylaws, and is immediately available on-

site overseeing the administration and monitoring of anesthesia personnel. Immediately available on-site means that the supervising physician is present and is available to respond and proceed immediately to the anesthetizing location.

"Universal precautions" means a set of precautions, in accordance with Centers for Disease Control and Prevention published guideline for Handwashing and Hospital Environmental Control. (Centers for Disease Control and Prevention Guideline for Prevention of Surgical Site Infections 1999 (Infection Control and Hospital Epidemiology 1999; 20:247-278), incorporated herein by reference, as amended and supplemented. That publication may be obtained by telephoning the Centers for Disease Control and Prevention at (800) 311-3435).

**8:43A-12.3 Surgical staff; qualifications**

- (a) There shall be a physician director who is clinically responsible for the surgical service and is board certified by the American Board of Medical Specialists.
- (b) Surgical procedures shall be performed only by practitioners who are licensed to practice in New Jersey and have been granted privileges to perform those procedures by the governing body of the facility, upon the recommendation of the medical staff, after medical review of each practitioner's documented education, training, experience, and current competence.
- (c) A physician and a registered professional nurse, at least one of whom maintains current training in Advanced Cardiac Life Support shall be present when surgery is in progress.

**8:43A-12.4 Anesthesia staff; qualifications**

- (a) There shall be a physician director of anesthesia services who is a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982. The medical director of the facility may serve as physician director of anesthesia services, if the medical director possesses the qualifications of a physician director of anesthesia services as specified in this subsection.
  - 1. Facilities in which only conscious sedation is administered may, in lieu of appointing a director of anesthesia services as specified in (a) above, ensure that each of the physicians who administer, supervise, or monitor the administration of conscious sedation in the facility is privileged by an acute care hospital, licensed in New Jersey in accordance with N.J.A.C. 8:43G, to administer, supervise, and monitor the administration of conscious sedation or credentialed in accordance with the provisions of N.J.A.C. 13:35-4A.10, Administration of conscious sedation; authorized personnel.
- (b) The physician director of anesthesia services shall participate in the credentialing

process and delineation of privileges of all personnel who administer anesthetic agents.

(c) All anesthesia providers who administer and/or supervise the administration of general anesthesia, major regional anesthesia, or conscious sedation anesthesia shall maintain current training in Advanced Cardiac Life Support.

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

**8:43A-12.5 Anesthesia staff; qualifications for supervising, administering, and monitoring anesthesia**

(a) General or major regional anesthesia shall be administered and monitored only by the following:

1. An anesthesiologist;
2. Under the supervision of an anesthesiologist:
  - i. A certified registered nurse anesthetist;
  - ii. A registered nurse anesthetist; or
  - iii. A physician resident, dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty;
3. Under the supervision of a privileged physician who has privileges in accordance with medical staff bylaws to administer or supervise the administration of anesthesia:
  - i. A certified registered nurse anesthetist; or
4. A dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology and has privileges in accordance with the ambulatory facility center's policy.

(b) The administration and monitoring of general or major regional anesthesia shall be provided by a qualified individual as described in (a)1 through 4 above, who is continuously present during the operation and is not performing or assisting with the procedure.

(c) The supervision of general or major regional anesthesia shall be provided by a physician who is immediately available. The supervising physician may concurrently be responsible for patient care, with the exception of, performing major surgery, administering general anesthesia, or major regional anesthesia.

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

1. A physician or dentist who has privileges in accordance with medical staff bylaws to administer anesthetic agents used for conscious sedation; or
2. Under the supervision of a physician who has privileges in accordance with medical staff bylaws to administer or supervise anesthetic agents used for conscious sedation who is immediately available:
  - i. A certified registered nurse anesthetist;
  - ii. A registered nurse anesthetist;
  - iii. A physician resident, dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or
  - iv. A registered nurse who is trained and experienced in the use of anesthetic agents used for conscious sedation shall be permitted to administer supplemental doses, after the initial dose is given by a privileged or supervising physician who shall remain present.

(e) The monitoring of patients who have been administered an anesthetic agent for the purpose of creating conscious sedation shall be provided by an individual who is continuously present for the primary purpose of anesthesia monitoring, who is separate from the individual performing the operation. This individual shall be currently trained in Advanced Cardiac Life Support and be one of the following:

1. One of the personnel identified in (d) above;
2. A registered professional nurse; or
3. For bronchoscopic procedures only, a licensed respiratory care therapist.

(f) Minor regional blocks shall be administered by the following:

1. A physician, podiatrist or dentist who has privileges in accordance with medical staff bylaws to administer minor regional blocks; or
2. Under the supervision of a physician who has privileges in accordance with medical staff bylaws to administer or supervise minor regional blocks and who is immediately available:
  - i. A certified registered nurse anesthetist;
  - ii. A registered nurse anesthetist



- iii. A physician resident, dental resident, or student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or
  - iv. A certified nurse midwife, a physician assistant, or an advanced practice nurse as permitted by the scope of practice rules of the New Jersey State Board of Medical Examiners and New Jersey State Board of Nursing, as applicable.
- (g) Minor regional blocks shall be monitored in accordance with the facility's policy.
- (h) Provision shall be made for remote monitoring of the patient if radiation or another direct hazard necessitates the removal of personnel.

**8:43A-12.6 Surgical policies and procedures**

- (a) The facility shall develop and implement written bylaws, rules, regulations, policies, and procedures for surgical and anesthesia services, in accordance with the governing authority and medical staff bylaws. The policies and procedures shall be reviewed at least every three years and revised as needed, and shall include at least the following:
1. Delineation of the surgical and anesthesia services which may be performed in the facility;
  2. Delineation of the responsibilities of medical staff members in providing care to patients;
  3. Designation of a time frame and of persons responsible for completing a medical history, physical examination, and laboratory tests prior to surgery;
  4. Policies and procedures regarding preanesthesia evaluation, patient preparation, and intraoperative management;
    - i. A patient identification system shall be implemented and patient identification shall be verified prior to any surgical procedure;
    - ii. There shall be a policy and procedure to verify the site and side of any and all surgical procedures. The procedure site and side shall be documented on the operative consent form.
    - iii. There shall be oral verification of the correct site and side of the surgical procedure in the operating room by a surgical team member in accordance with the facility's policy;
  5. Policies and procedures to ensure that every patient is examined by a practitioner immediately prior to surgery;

6. A registered professional nurse shall be assigned to circulating nurse duties in each room where surgery is being performed;
7. Policies and procedures for use of analgesia and anesthesia, including types which may be used for each procedure, safety regulations, and responsibilities and qualifications of persons who administer anesthesia and monitor patients;
8. Policies and procedures for the preoperative and postoperative recording of vital signs (blood pressure, temperature, pulse and respiration rate);
9. Policies for reporting of morbidity and mortality in accordance with N.J.A.C; 8:43A-12.7(b);
10. Policies and procedures for monitoring of patients in any special procedure room or other location where patients receive anesthesia;
11. Policies and procedures for postoperative observation and care required for each type of procedure;
12. Methods to ensure that gross and microscopic tissue removed surgically or by any other procedure, including termination of pregnancy in accordance with the regulations of the New Jersey State Board of Medical Examiners, N.J.A.C. 13:35-4.2, is examined by a pathologist and a report of the findings is documented in the patient's medical record;
  - i. The facility shall ensure that the tissue is disposed of in accordance with N.J.A.C. 8:43A-14.7 of this chapter whether it is examined on the facility's premises or off the facility's premises;
13. Specification of the duration of time the patient shall remain in the facility after surgery; Policies for discharge criteria from the facility;
14. Requirements for written documentation of surgical procedures performed, including at least a description of the findings, procedures used, specimens removed, patient's condition, any unusual events occurring during the procedure, postoperative diagnosis, and names of the surgeon and assistants. This operative note shall be written or dictated immediately following the procedure by the person performing the surgery and incorporated into the patient's medical record;
15. Policies and procedures for the provision of written instructions to the patient (multilingual, if indicated) on preoperative and postoperative care, including, but not limited to, restrictions on food and beverages before surgery and procedures for obtaining help in the event of surgical wound infection or other postoperative problems;
16. Policies and procedures regarding infection prevention and control, shall be

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reviewed at least every three years and revised more frequently if needed, including, but not limited to, the following:

- i. Designation of a person with training or experience in surveillance, prevention, and control of nosocomial infection who is responsible for the direction, provision, and quality of infection prevention and control services;
  - ii. Use of aseptic technique and scrub procedures;
  - iii. Detailed specification of attire in all the operative areas according to facility infection control policies, to include at a minimum the commercial laundering of scrub attire between uses;
  - iv. Traffic control, including restricted access to the surgical suite;
  - v. Cleaning of the operating room after each procedure including documentation of training in cleaning the surgical suite and the specific assignment of this task thereafter by individuals who are trained;
  - vi. Care of operating room equipment and anesthesia equipment; and
  - vii. A written procedure for the handling of soiled laundry and trash which shall be bagged and collected at the termination of each procedure and transported to the soiled holding area;
  - viii. A written procedure for the handling of soiled laundry and trash, which shall be placed in closed containers in each operating room. Medical waste and sharps shall be handled in accordance with current applicable State and Federal rules and regulations.
17. All surgical staff shall comply with the universal precautions set forth in the Centers for Disease Control and Prevention Guideline for Handwashing and Hospital Environmental Control. (Centers for Disease Control and Prevention Guideline for Prevention of Surgical Site Infection (1999; 20:247-278), incorporated herein by reference, as amended and supplemented. That publication may be obtained by telephoning the Centers for Disease Control and Prevention at (800) 311-3435.)

#### **8:43A-12.7 Anesthesia continuous quality improvement**

- (a) The facility's quality improvement program shall include a systematic review and evaluation of patient care, anesthesia practices and anesthesia techniques. The surgical staff shall identify problem-prone processes, which manifest undesirable patterns. The facility shall develop a plan by which to collect and analyze data in order to evaluate outcomes or performance of the problem-prone processes. Data analysis shall focus on recommendations for implementing corrective actions and improving performance.

(b) Continuous quality improvement shall include morbidity and mortality conferences.

(c) The facility shall notify the New Jersey Department of Health and Senior Services, Inspections, Compliance and Complaints Program, by telephone at (609) 292-9900 or (800) 792-9770 or by fax at (609) 943-3013 within 24 hours, and in writing within 30 days, of all deaths in anesthetizing locations and unexpected intraoperative or postoperative events or outcomes related to anesthesia, except those in which the patient expired prior to the administration of anesthesia.

1. The written report shall be submitted on the form entitled "Confidential Report of Anesthesia-Related Incident" (HFE-5), available from the New Jersey Department of Health and Senior Services and shall include:

i. A summary of the incident and the patient's risk status or the American Society of Anesthesiology (ASA) Physical Status Classification; and

ii. All unexpected intraoperative or postoperative events or outcomes related to anesthesia.

#### **8:43A-12.8 Records**

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

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

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

(d) Upon arrival in the postanesthesia care unit, a postanesthesia note shall be entered into the patient's anesthesia record by a member of the facility's anesthesia team.

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

(f) A discharge note shall be entered into the patient's medical record by an anesthesia team member prior to discharge from the facility.

**8:43A-12.9 Surgical service emergency equipment**

- (a) Emergency equipment available to the operating room in a surgical service shall include at least the following:
1. Emergency call system to include, at least an emergency communication system that connects each operating room and postanesthesia care unit with the control center of the suite;
  2. Oxygen;
  3. Difficult airway container or cart shall be immediately available for handling emergencies. The emergency equipment shall include, but not be limited to, resuscitation equipment, and equipment to open and maintain an airway;
  4. Cardiac defibrillator;
  5. Cardiac monitoring equipment;
  6. Tracheostomy set including sizes adaptable to children; Sizes for newborns and infants shall be made available, unless a facility's policy explicitly excludes the provision of services for this population.
  7. Laryngoscopes and endotracheal tubes including sizes adaptable to children; Sizes for newborns and infants shall be made available, unless a facility's policy explicitly excludes the provision of services for this population.
  8. Portable suction equipment with catheter tip;
  9. Emergency drugs and supplies specified by the medical staff in the facility's policies and procedures; and
  10. There shall be a mechanism for testing the emergency equipment on a regular basis and documenting that it is in working condition.

**8:43A-12.10 Anesthesia supplies and equipment; safety systems**

- (a) Diameter index safety systems or equivalent systems shall be used on all large cylinders of medical gases, and wall and ceiling outlets of medical gases.
- (b) Pin index safety systems with a single washer shall be used on all small cylinders to prevent interchangeability of medical gas cylinders.
- (c) All medical gas hoses and adapters shall be color-coded and labeled according to current national standards, that is, the Compressed Gas Association: Standard color marking for compressed gas containers intended for medical use, as well as clear labeling. Publication (C-9) (ed 3), Arlington, VA, 1988, incorporated herein by

reference, as amended and supplemented. That publication may be obtained by telephoning the Compressed Gas Association at (703) 412-0900.

- (d) An oxygen failure-protection device ("fail-safe" system) shall be used on all anesthesia machines to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced.
- (e) A vaporizer exclusion ("interlock") system shall be used to assure that only one vaporizer, and therefore only a single agent, can be actuated on any anesthesia machine at one time.
- (f) To prevent delivery of excess anesthesia during an oxygen flush, no vaporizer shall be placed in the circuit downstream of the oxygen flush valve.
- (g) All anesthesia vaporizers shall be pressure-compensated in order to administer a constant non-pulsatile output.
- (h) Accurate flow meters and controllers shall be used to prevent the delivery to a patient of an inadequate concentration of oxygen relative to the amount of nitrous oxide or other medical gas.
- (i) Alarm systems shall be in place for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia.
- (j) There shall be a written protocol to assure that surgery does not proceed when there are disabled alarms, depleted batteries and inactive sensors in oxygen monitors, carbon dioxide monitors or improperly positioned breathing-circuit sensors, or other insufficiencies.

**8:43A-12.11 Anesthesia supplies and equipment; maintenance and inspections**

- (a) A record shall be maintained of all service and maintenance performed on all anesthesia machines, ventilators, and vaporizers. The record shall include machine identification; the name of the servicing agent; the work performed; and the date of the work. This maintenance shall conform with maintenance requirements established by the machine manufacturer. Credentials of each servicing agent shall be approved by the machine manufacturer or shall be determined by the physician director of anesthesia services as equivalent to the credentials of manufacturers' servicing agents.
- (b) All anesthesia equipment shall be inspected fully at the beginning of each day of use. A record of each such inspection shall be maintained for each machine. The inspection shall conform with a checklist that is supplied by the manufacturer of the machine, issued by the Federal Food and Drug Administration, or, alternatively, developed by the facility's anesthesia services and approved by the physician director of anesthesia services.

(c) All anesthesia equipment shall be inspected before each use. A record of each inspection shall be indicated on the patient's anesthesia record. Each record may consist of a checklist or single phrase explanation.

**8:43A-12.12 Anesthesia supplies and equipment; patient monitoring**

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

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

(c) The body temperature of each patient under general or major regional anesthesia lasting 45 minutes or more shall be continuously monitored and recorded at least every 15 minutes.

(d) Pulse oximetry shall be performed continuously during administration of general anesthesia, regional anesthesia, or conscious sedation, at all anesthetizing locations, unless such monitoring is not clinically feasible for the patient. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness.

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

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

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

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

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

(j) Monitoring of regional labor analgesia shall include: documented temperature, pulse, respiration, blood pressure, and oxygen saturation until the patient is deemed

stable based on written criteria established by the Department of Anesthesia. The patient shall be subsequently monitored in accordance with facility protocol.

(k) Supplemental oxygen and a delivery system appropriate to the patient's condition shall be immediately available for patient transport from the operating room to the postanesthesia care unit.

#### **8:43A-12.13 Anesthesia staff education and training**

(a) Staff education programs and training sessions shall include patient safety and the inspection and use of equipment.

(b) Requirements for the anesthesia education program shall be as set forth in N.J.A.C. 8:43G-5.9.

#### **8:43A-12.14 Postanesthesia care policies and procedures**

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

(b) The postanesthesia care unit shall have written policies and procedures that are reviewed at least every three years, revised more frequently as needed, and implemented. These shall include at least:

1. Criteria for admission to and discharge from the unit;
2. Delineation of the primary medical responsibility for postanesthesia and postsurgical care of each patient in the unit, including authority to discharge;
3. Monitoring of patients in the postanesthesia care unit, including availability of monitoring equipment;
4. Protocol of care for all patients;
5. Protocol for patient emergencies;
6. Orders for intravenous administration of medications;
7. Requirements for documentation of patient status; and
8. A requirement that patients who receive anesthesia, excluding minor regional blocks, do not drive themselves home after discharge and that they be accompanied home by another person who accepts responsibility for the patient. If the patient fails to comply with the requirement, the circumstances shall be documented in the patient's medical record.

#### **8:43A-12.15 Postanesthesia care staff qualifications**

(a) There shall be a physician director with overall responsibility for postanesthesia



care. The physician director of anesthesia services may serve as physician director of postanesthesia care.

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

(c) Documentation shall be available to show that all registered professional nurses assigned to the postanesthesia care unit meet the minimum competence levels, including at least:

1. Management of airway and ventilatory function;
2. Monitoring of cardiac function, arrhythmia recognition, and treatment of life-threatening emergencies;
3. Management of the patient during altered states of consciousness;
4. Management of monitoring and respiratory equipment;
5. Management of fluid lines, tubes, drains, and catheters;
6. Administration of drugs and identification of drug-related problems; and
7. Recognition of the actions and interactions of anesthetic techniques.

(d) All registered professional nurses in the postanesthesia care unit shall maintain current training in Advanced Cardiac Life Support.

**8:43A-12.16 Postanesthesia care staff time and availability**

There shall be at least one registered professional nurse present whenever a patient is in the postanesthesia care unit, and a second health care staff member shall be immediately available.

**8:43A-12.17 Postanesthesia care patient services**

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

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

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

- (c) A member of the anesthesia team shall stay with the patient in the postanesthesia care unit at least until the patient's vital signs, including temperature, pulse, respiration and blood pressure are recorded.
- (d) The postanesthesia care unit staff shall continually evaluate the condition of each patient and maintain an accurate written report of his or her vital signs, with an objective scoring system used to track the patient's recovery from anesthesia from the time of admission to the unit until discharge.
- (e) Electrocardiographic monitoring shall be conducted for each patient, who has received general anesthesia or regional anesthesia, unless such monitoring is not clinically feasible for the patient.
- (f) Each patient who has received general anesthesia or regional anesthesia shall be monitored by pulse oximetry, unless such monitoring is not clinically feasible for the patient.
- (g) The postanesthesia care unit shall have immediate access to end-tidal carbon dioxide monitoring, if general anesthesia is administered to intubated patients in the facility.
- (h) The Post Anesthesia Care Unit record maintained for each patient in the postanesthesia care unit shall include at least such preoperative data as: allergies, physical and mental impairments, prostheses, vital signs, drug use, mobility limitations, and when indicated radiologic findings, laboratory values, and electrocardiogram.
- (i) The Post Anesthesia Care Unit record maintained for each patient in the postanesthesia care shall include at least such postoperative data as: the patient's general condition, temperature, pulse, respiration, blood pressure, level of consciousness, circulation, special problems or precautions, summary of fluids received during surgery, and oxygen saturation.
- (j) Patients shall be discharged from the postanesthesia care unit using discharge criteria, including authority to discharge, which have been developed through the postanesthesia policies and procedures set forth at N.J.A.C. 8:43A-12.14(b).

**8:43A-12.18 Postanesthesia care units and equipment**

- (a) Postanesthesia care units shall be adjacent to or within the operating suite.
- (b) The postanesthesia care unit shall be maintained as a closed unit. Access to the 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.

#### **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.

#### **8:43A-12.20 Physical plant**

- (a) New ambulatory surgical facilities shall comply with Chapter 3.7 (Outpatient Surgical Facility) of the construction guidelines.
- (b) When the ambulatory surgical facility is part of an acute care hospital's surgical suite, support services may be shared to avoid duplication. When inpatients and outpatients are served in the same suite, the functional program shall describe in detail scheduling and techniques used to separate inpatients from outpatients.

#### **8:43A-12.21 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, 21.6(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.

## **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;

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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.

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**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 as 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, domestic partner, civil union partner, 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 that 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).

### **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 measure 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

**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 listed below, incorporated herein by reference, as amended and supplemented:

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. Guidelines for Preventing Health-Care-Associated Pneumonia, 2003: Recommendation of CDC and the Healthcare Infection Control Practices Advisory Committee, published in the Morbidity and Mortality Weekly Report at MMWR 2004; 53 (No. RR-3), published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5303.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm>;
5. Guideline for Hand Hygiene in Health-Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, published in the Morbidity and Mortality Weekly Report at MMWR 2002; 51 (No. RR-16), published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>;
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 web site 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>.

(c) The Department shall allow facilities to diverge from the guidelines and recommendations listed at (a) above, provided that there is a sound infection control rationale based upon scientific research or epidemiologic data for the diversion.

#### **8:43A-14.4 Sterilization of patient care items**

(a) Methods for processing reusable medical devices shall conform with the following documents, incorporated herein by reference, as amended and supplemented:

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 Glutaraldehyde-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;
6. 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;
7. 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;
8. 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

9. Society of Gastroenterology Nurses and Associates (SGNA), “Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes,” (2000).
- (b) The documents referenced in (a) 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](http://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](http://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 perform its sterile reprocessing, 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.

**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).

#### **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.

**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).

**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 procedures 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 licensee shall file the written, comprehensive emergency plan with the Department, and shall notify the Department when the plan is changed.

1. The licensee shall submit the plan 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 semi-annual visual inspections and annual operational tests of the building's manual pull alarm system and shall maintain documentation of inspections, 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.

i. 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 Department for statutorily authorized purposes.

ii. 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.

**8:43A-16.3 Notice**

(a) The administrator shall provide all patients and/or their families upon request the name, addresses, and telephone numbers of the following offices with which complaints may be lodged: the Office of Acute Care Assessment and Survey and the Office of the Ombudsman for the Institutionalized Elderly.

(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.

### **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.

### **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.



- (c) All household and cleaning products in the facility shall be identified, labeled, and securely stored in a cabinet, closet, or room which is inaccessible to patients.
- (d) Housekeeping and cleaning supplies shall be selected and approved by the Infection Control Committee. They shall be measured and used correctly according to the manufacturers' written instructions.
- (e) All toilets and bathrooms shall be kept clean to sight and touch, in good repair, and free of odors that reflect poor housekeeping practices.
- (f) Toilet tissue, soap, and disposable towels or air driers shall be provided in each bathroom at all times. Soap and disposable towels or air driers shall be provided at each handwashing sink at all times.
- (g) Reusable hand-cleanser dispensers shall be clean inside and out. Disposable dispensers shall be discarded and not refilled.
- (h) Carpeting shall be kept clean and odor-free and shall not be frayed, worn, torn, or buckled.
- (i) Window and partitioning curtains and drapes shall be kept clean to sight and touch and odor-free.
- (j) Walls, ceilings, and vents shall be kept clean to sight and touch and odor-free.
- (k) Windows and screens shall be kept clean to sight and touch and in good repair.
- (l) Effective and safe controls shall be used to minimize and eliminate the presence of rodents, flies, roaches and other vermin in the facility. The premises shall be kept in such condition as to prevent the breeding, harborage, or feeding of vermin. All openings to the outer air shall be effectively protected against the entrance of insects.
- (m) Nonskid wax shall be used on all waxed floors.
- (n) All communal toys shall be washed after each use. No stuffed animals shall be allowed except for personal use.
- (o) Plants and flowers shall not be allowed in patient treatment areas (such as operating rooms and procedure rooms) or sterile processing areas.

#### **8:43A-17.4 Environmental patient care services**

- (a) The following environmental conditions shall be met:
  - 1. Thermometers which are accurate to within three degrees Fahrenheit shall be

- kept in a visible location in refrigerators, freezers, and storerooms used for perishable and other items subject to deterioration. Records shall be kept for 12 months;
2. Articles in storage shall be elevated from the floor and away from walls, ceilings, and air vents to facilitate cleaning. Storage units shall be non-porous and cleanable;
  3. There shall be separate refrigerators for medications, laboratory specimens, and food. There shall be a separate designated area for all food items and beverages. Records shall be kept for 12 months;
  4. Draperies, upholstery, and other fabrics or decorations shall be fire-resistant and flameproof;
  5. Latex foam pillows shall be prohibited;
  6. Equipment requiring drainage shall be drained to a sanitary connection, in accordance with State and local codes;
  7. During warm weather conditions, the temperature of the facility shall not exceed 82 degrees Fahrenheit. The facility shall establish a written heat emergency action plan which specifies procedures to be followed in the event that the indoor air temperature is 82 degrees Fahrenheit or higher for a continuous period of four hours or longer. The facility shall provide adequate ventilation in all areas used by patients;
  8. The temperature in the facility shall be kept at a minimum of 72 degrees Fahrenheit (22 degrees Celsius) when patients are in the facility;
  9. Throw rugs or scatter rugs shall not be used in the facility;
  10. All equipment shall have unobstructed space provided for operation;
  11. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement;
  12. Paints, varnishes, lacquers, thinners, and all other flammable materials shall be stored outside the building. Minimum supplies may be kept in the building in a locked storage room or in closed, locked metal cabinets or containers in a non-patient area of the facility;
  13. All furnishings shall be clean and in good repair, and mechanical equipment shall be in good working order. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection. Broken or worn items shall be repaired, replaced, or removed promptly;

14. Mattresses, mattress pads and coverings, pillows, bedsprings, and other furnishings shall be properly maintained and kept clean. They shall be thoroughly cleaned and disinfected upon discharge of each patient;

15. All equipment and environmental surfaces shall be kept clean to sight and touch; and

16. When areas of the facility are undergoing renovation or new construction, protective measures shall be taken to contain dust and redirect traffic in patient care areas.

#### **8:43A-17.5 Regulated medical waste and solid waste management**

(a) Policies and procedures for solid waste and recyclables shall be established and enforced to ensure appropriate collection, storage and disposal and to maintain them clean and odor-free and to prevent the breeding of insects or vermin.

1. Plastic bags shall be used for solid waste removal from patient care units and support departments. Bags shall be of sufficient strength to safely contain waste from point of origin to point of disposal and shall be effectively closed prior to disposal.

2. Outside storage containers for solid waste shall be kept covered, except those used for corrugated cardboard, recyclables, or construction materials.

3. Garbage compactors shall be located on an impervious pad that is graded to a drain. The drain shall be kept clean and shall be connected to the sanitary sewage disposal system.

4. All solid waste that is not regulated medical waste shall still be disposed of in a manner approved by the New Jersey Department of Environmental Protection. Disposal shall be as frequent as necessary to avoid creating a nuisance.

5. Indoor storage containers for solid waste shall be fireproof and kept covered when necessary to control odors or other nuisances.

6. Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from the storage area regularly to prevent nuisances such as odors, flies, other vermin, or rodents, and so that waste does not overflow or accumulate beyond the capacity of the storage containers.

(b) The facility shall comply with the provisions of N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Medical Waste Management Act, and all rules promulgated pursuant to the aforementioned act.

(c) All liquid waste shall be collected, stored, and disposed of in accordance with the rules of the New Jersey Department of Environmental Protection.

**8:43A-17.6 (Reserved)**

## **SUBCHAPTER 18. QUALITY ASSURANCE PROGRAM**

### **8:43A-18.1 Quality assurance plan**

- (a) The facility shall establish and implement a written plan for a quality assurance program for patient care. The quality assurance plan shall be reviewed at least annually and revised as necessary. The plan shall specify a timetable and the individual responsible for coordinating the quality assurance program and shall provide for ongoing monitoring of staff and patient care services.
- (b) There shall be a multidisciplinary committee responsible for the direction of the quality assurance program. The committee shall include at least representation from the medical staff, nursing staff and administration. The committee shall establish a mechanism to include participation of all disciplines in the identification of areas for review that affect patient care throughout the facility.

### **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, and the construction guidelines.
- (b) New buildings and alterations and additions to existing buildings for ambulatory care facilities that are part of an acute care hospital shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23, and the construction guidelines.

### **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 submission; payment of review fees**

- (a) Prior to any construction, plans shall be submitted for review and approval, in accordance with the provisions of this chapter, to the Healthcare Plan Review Unit.
- (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 Barrier-Free Subcode of the New Jersey Uniform Construction Code, N.J.A.C. 5:23-7.

**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 3.1 (Outpatient Facilities) of the construction guidelines.

**8:43A-19.7 Small ambulatory care facilities**

(a) For purposes of this section, "small ambulatory care facility" means a facility that provides ambulatory care services at which four or fewer workers use the space and equipment at any one time.

(b) Chapter 3.3 (Small Primary (Neighborhood) Outpatient Facilities) of the construction guidelines applies to new small ambulatory care facilities.

**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.



**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 Primary care outpatient facilities**

New facilities that provide primary care services, except small facilities addressed at N.J.A.C. 8:43A-23.5, shall comply with Chapter 3.2 of the construction guidelines.

**8:43A-23.5 Small primary care outpatient facilities**

(a) For purposes of this section, "small primary care outpatient facility" means a facility that provides primary care services at which four or fewer workers use the space and equipment at any one time.

(b) 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.

(c) New small primary care outpatient facilities shall comply with Chapter 3.2 of the construction guidelines.

**SUBCHAPTER 24. CHRONIC DIALYSIS SERVICES****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 current edition of 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 or 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 qualifications:
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-1.10, 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;
    - 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,” 2<sup>nd</sup> Edition and Amendment, RD16:1996 and AI:2002, “Hemodialyzer blood tubing,” 2<sup>nd</sup> Edition and Amendment, RD17:1994 and AI:2002, and “Reuse of hemodialyzers,” 3<sup>rd</sup> Edition and Amendment, RD47:2002 and AI: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 publications entitled, "Water treatment equipment for hemodialysis applications," RD62:2006, "Dialysate for hemodialysis," RD52:2004, "Hemodialysis systems," RD5:2003, and "Concentrates for hemodialysis," RD61:2000, incorporated herein by reference, as amended and supplemented.

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 ten 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 USCS § 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 registered 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 dietician 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-13.1 et seq., 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;
    - 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 (b)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 (b)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.
  - i. This dimensional requirement shall apply to those facilities licensed March 6, 2006 or later.
  - ii. 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 this section.
- (e) There shall be a separate soiled utility room within the ambulatory dialysis suite.
  1. The soiled utility room shall contain a minimum of 120 square feet and shall contain a sink equipped for handwashing.
    - i. This dimensional requirement shall apply to those facilities licensed March 6, 2006 and thereafter.
    - ii. 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 this section.
- (f) A separate janitors' closet shall be provided exclusively for the ambulatory dialysis suite.
  1. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.
- (g) A separate, handicapped accessible toilet room with handwashing facilities shall be provided for patients.
  1. Each 21 station increment requires a minimum of one handicapped-accessible toilet to be provided.
  2. Toilet room locations shall be distributed throughout the treatment area for patient access.
- (h) A staff breakroom/lounge/locker room shall contain a sink, a workcounter, a refrigerator, storage cabinets and equipment for serving nourishments, as clinically required by the patient.
  1. Toilet facilities with handwashing facilities shall also be provided.
  2. The breakroom/lounge/locker room shall be sized in accordance with the anticipated amount of employees.

- (i) The nurses' station shall be designed and located so as to permit visual observation of each patient station.
- (j) Door(s) to patients' toilet room(s) shall be equipped with hardware which permits access from the exterior by staff in any emergency.
- (k) If home training rooms are provided, each room shall be equipped with a sink for handwashing.
- (l) If chronic kidney disease counseling (CKD) services are provided, the facility shall provide space for the provision of CKD counseling services which affords patient privacy and which is separate from the hemodialysis treatment area(s).
- (m) Storage space shall be provided for wheelchairs and stretchers out of the direct line of traffic to permit unobstructed egress.
- (n) A room shall be provided for storage of equipment used in the patient care area.
- (o) An examination room shall be provided with a minimum of 80 square feet of clear floor area exclusive of the work counter and lavatory for handwashing.
  - 1. Facilities licensed by March 6, 2006, shall not be subject to the dimensional requirements of this provision.
  - 2. 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 herein.
- (p) Office space shall be provided for administration, medical and nursing services, social work services, and dietary counseling services.
- (q) Space for conferences, consultation, and other purposes shall be provided.
- (r) A waiting area with access to a telephone, toilet facilities, and a drinking fountain shall be provided.
- (s) Each toilet facility for patients shall be served by an emergency call system. Calls shall activate a signal at the nurses' station.
- (t) There shall be a medication administration station for the ambulatory dialysis service.
  - 1. The medication administration station shall contain handwashing facilities, a work counter, a refrigerator, and locked storage for biologicals, medications, and syringes.

- i. Provisions shall be made for the controlled storage, preparation, and administration of medications.
2. Each 21-station increment requires a minimum of one drug distribution station.
  - i. The distribution stations shall be interspersed throughout the treatment area for easy staff access.
- (u) Patient records shall be kept in a secure area.

**8:43A-24.16 Emergency generator and water supply**

- (a) An emergency generator shall be provided in a room which shall have a one-hour fire rating with an approved fresh air intake and an explosion release. All machines shall be connected to the emergency generator so that all machines will operate for at least four hours following a power shutdown or outage

**8:43A-24.17 Requirements for pediatric dialysis services**

- (a) The physical plant requirements for pediatric dialysis services shall be established as follows:
  1. If pediatric dialysis services are provided, they shall be located in a treatment area separate from the services provided to adults except if peritoneal dialysis is the service in which case, training and back-up care may be integrated into an adult unit. Pediatric patients are defined as patients who are less than fourteen (14) years of age.
  2. The area housing the pediatric dialysis unit shall be enclosed with fixed partitions that extend from finished floor to ceiling. Vision panels in partitions are required.
  3. The pediatric dialysis unit shall have handwashing facilities that are separate from the adult unit.
  4. If pediatric patients are treated, the facility shall use equipment, supplies, and emergency devices to include blood pressure cuffs, dialyzers, and bloodlines approved for use on pediatric patients.
- (b) All patients admitted to the facility under the age of 18 for renal dialysis services shall be evaluated by a pediatric nephrologist. Any patient 13 years old or under shall be under the care of a pediatric nephrologist at all times. After the initial evaluation and at the discretion of the pediatric nephrologist, the treatment of patients 14 -18 years

old may be referred to nephrologists who specialize in the care of adult dialysis patients.

(c) The requirements for nursing care shall be established as follows:

1. The facility shall maintain documentation of competencies in general pediatrics and/or pediatric nephrology for all licensed professional nurses responsible for providing care to a pediatric renal patient. Such individuals shall demonstrate current competencies in pediatric care.
2. Patients age 13 and under must be dialyzed by a registered nurse.
3. Patients over the age of 13 and whose weight is greater than 30 kilograms may be dialyzed by a licensed practical nurse or patient care technician only after a registered nurse has assessed this patient and only under the supervision of a registered nurse.
4. All patient assessments are the responsibility of the registered nurse.
5. Nurse-patient ratios shall be established as follows :
  - i. For patients whose weight is less than 20 kilograms, the nurse patient ratio shall be one to one.
  - ii. For patients whose weight is 20 to 40 kilograms, the nurse-patient ratio shall be one to two;
  - iii. For patients whose weight is greater than 40 kilograms, the nurse-patient ratio shall be one to three.

(d) The pediatric care plan shall be established as follows:

1. The pediatric care plan shall be developed by a multidisciplinary team as set forth in N.J.A.C. 8:43G-30.12.
  - i. The pediatric patient care plan shall address those issues specific to but not limited to growth and development, nutrition, and patient and family education.
  - ii. All pediatric renal patients shall be seen and evaluated by a transplantation team within 90 days of admission.

(e) The requirements for infection control practices and procedures shall be established as follows:

1. Patients shall receive all age appropriate immunizations with documentation noted in the record. If immunizations are not administered, the reasons must be documented.
2. Varicella vaccine shall be administered to all patients over the age of 12 months or more who have not had documented varicella infection or documented varicella antibody titer.

#### **8:43A-24.18 Renal dialysis quality assurance plan**

- (a) In addition to the requirements set forth in N.J.A.C. 8:43A-18, the facility shall develop a quality assurance plan that includes all areas of service, management and operations, which shall be monitored by the governing body.
- (b) The governing body is responsible for the following:
  1. Establishment of program goals and objectives;
  2. Oversight of program implementation, revision and effectiveness;
  3. Allocation of sufficient time and resources to accomplish objectives and attain goals;
  4. Inclusion of all attending physicians and other categorical key personnel in program operation; and
  5. Quality assurance activities shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate implementation until resolution is achieved.
- (c) At a minimum, the quality assurance plan shall analyze those indicators required by the Trans-Atlantic Renal Council (109 South Main Street, Cranbury, New Jersey 08512).

These indicators can be found in the Medicare ESRD Network Organizations Manual (Revision 2, September 12, 2003), incorporated herein by reference, as amended and supplemented, which is available for download from the Centers for Medicare and Medicaid Services website at [www.cms.hhs.gov/esrd/2.asp](http://www.cms.hhs.gov/esrd/2.asp) and upon request to the Department by telephoning (609) 292-5960.
- (d) Meetings of the quality assurance and performance improvement committee shall be held at least quarterly and shall be separate from other patient care or management meetings. Written minutes of each meeting shall be maintained; these minutes shall include a formal agenda, attendance record, items considered, action decided and review of actions implemented. Minutes and other material considered during the

meeting shall be kept on file, provided to the governing body in a timely manner, and readily available for at least the previous seven quarters.

#### **8:43A-24.19 Consultant pharmacist**

(a) The facility shall retain a consultant pharmacist who has no affiliation with the pharmacy that provides services to the facility, the facility in which services are provided, or any of their affiliates. The consultant pharmacists' responsibilities shall include, but not be limited to:

1. Development and/or review of all facility policies and procedures regarding pharmaceutical services. Policies and procedures shall include the development and maintenance of written objectives, an organizational plan and continuous quality improvement regarding the administration, storage, control and disposition of medications at the facility;
2. Offering educational programs in pharmacology to facility staff at the request of the facility administrator, director of nursing, or as required by the use of new medication systems, pharmacological innovations or advances in technology;
3. Conducting individual drug regimen reviews and providing pertinent information related, but not limited to, potential adverse reactions, drug interactions, medication dosage, pharmacokinetics, pharmacodynamics, pharmacoeconomics, at the request of the facility administrator;
4. At a minimum, conducting quarterly reviews of medical records and all areas in the facility in which medications are dispensed, administered, stored, or destroyed, document any problems, and propose solutions to problems; and
5. Submitting written reports, at least quarterly, to the administrator and the medical director.

#### **8:43A-24.20 Home care dialysis services**

(a) If home (self) care dialysis services are provided, the facility shall establish, implement, and review, at least annually, written policies and procedures including, but not limited to, policies and procedures for the following:

1. Development of a written outline of the home (self) care training program, including didactic and practical sessions, for the unsupervised performance of dialysis treatments by patients and family;
2. A home visitation program, in which a registered professional nurse assesses the physical environment of the home, the patient's ability to perform home

dialysis treatments, and the level of support that is available to the patient from family members or significant others;

3. Availability of teaching materials for patient use during and after home (self) care dialysis training and at times other than during the dialysis procedure;
4. Provision of consultation to the patient by a social worker and a dietitian;
5. Installation and maintenance of equipment in the home;
6. Testing and treatment of the water in the home; and
7. Ordering of supplies for the home on an ongoing basis.

**8:43A-24.21 Chronic kidney disease counseling services**

(a) If chronic kidney disease (CKD) counseling services are provided, the facility shall establish, implement and review, at least every three years, written policies and procedures which shall include at least the following:

1. Development of a patient educational program which shall include, but is not limited to, the following:
  - i. Prevention/treatment of complications of CKD (that is, hypertension, anemia, malnutrition, bone disease);
  - ii. Treatment of cardiovascular disease and diabetes;
  - iii. Renal replacement therapy options (that is, hemodialysis, peritoneal dialysis, transplantation);
  - iv. Improvement of personal health (for example, diet and exercise); and
  - v. Preparation for dialysis (that is, arm preservation, vascular access planning).
2. Delineation of the teaching/educational materials which shall be distributed to the patient;
3. Documentation in the medical record of the type, content and frequency of the CKD services provided; and

(b) A registered professional nurse shall direct the CKD counseling services and shall be present at the facility during the time such services are provided to patients.

(c) The facility shall ensure that evaluation and counseling services are provided by a multidisciplinary team, which shall include a nephrologist, a registered professional nurse, a dietitian, and a social worker.

(d) The multidisciplinary team shall develop an individualized plan of care for CKD counseling services and any related health care services provided.



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

**8:43A-25.1 Additional requirements and exceptions**

- (a) An ambulatory care facility which provides computerized tomography, magnetic resonance imaging, or radiological services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter. If the facility also provides surgical or anesthesia services, then the facility shall also comply with N.J.A.C. 8:43A-12.
1. An ambulatory care facility which provides only computerized tomography, magnetic resonance imaging, or radiological services need not comply with N.J.A.C. 8:43A-3.6(a)6, 13.3(a)7 and 13.3(a)8 for the purpose of licensure.
  2. If the facility provides only computerized tomography, magnetic resonance imaging, or radiological services, a radiologic technologist may satisfy the requirement for an administrator at N.J.A.C. 8:43A-5.1.
  3. If the facility provides only computerized tomography, magnetic resonance imaging, or radiological services, the part of N.J.A.C. 8:43A-3.1(a) which requires nursing services to be provided in the facility shall not apply, unless nursing services are ordered by a physician.
  4. If the facility provides only computerized tomography, magnetic resonance imaging, or radiological services, the part of N.J.A.C. 8:43A-6.2(a) which requires a representative of the nursing staff to serve on the patient care policy committee shall not apply.
  5. If the facility provides only computerized tomography, magnetic resonance imaging, or radiological services, the part of N.J.A.C. 8:43A-18.1(b) which requires a representative of the nursing service to serve on the committee responsible for the quality assurance program shall not apply.
  6. An ambulatory care facility which provides only computerized tomography, magnetic resonance imaging, or radiological services may satisfy the requirements of N.J.A.C. 8:43A-14.2 for an infection control committee by requiring the person responsible for the infection prevention and control program to ensure that the medical director and other professional staff participate in the development and implementation of the program, including the development, implementation, and review of the policies and procedures required by N.J.A.C. 8:43A-14.2(b).
  7. If the facility provides only computerized tomography, magnetic resonance imaging, or radiological services, the part of N.J.A.C. 8:43A-3.1(a) which requires counseling services to be provided directly by the facility or through

written agreement shall not apply.

**8:43A-25.2 Additional staffing**

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

1. One radiologist available during the facility's hours of operation and on the premises whenever a contrast medium is being used;
2. One radiologic technologist on the premises during the facility's hours of operation; and
3. A radiation physicist/health physicist who shall be available for safety evaluations of equipment and of storage and handling practices, and for staff education.

(b) In addition to providing other staff as required by this chapter, a facility providing magnetic resonance imaging services shall have at least the following staff:

1. A medical director available who is a radiologist and whose primary responsibility during the last three years has been in the interpretation of cross-sectional imaging for all body areas. ("Available" means capable of being reached);
2. One radiologist available during the facility's hours of operation and on the premises whenever a contrast medium is being used;
3. One full-time equivalent technician with documented training and experience in MRI service delivery and one other staff member, both of whom shall be on the premises during the facility's hours of operation; and
4. A radiation physicist/health physicist with documented training and experience in MRI techniques who shall be available.

(c) In addition to providing other staff as required by the rules in this chapter, a facility providing radiological services directly in the facility shall have a radiologist available. ("Available" means capable of being reached.) Radiologists shall supervise and interpret all radiologic procedures, unless performed by clinical practitioners in specialty areas who are trained and experienced in these procedures.

**8:43A-25.3 Safety**

A facility providing magnetic resonance imaging (MRI), computerized tomography, or other diagnostic services shall develop and implement policies and procedures intended to ensure patient safety during use of all diagnostic equipment.

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

(a) A new ambulatory care facility that provides computerized tomography or magnetic resonance imaging services shall comply with Sections 3.1-2.2 and 2.1-5.5 of the construction guidelines.

(b) Existing facilities shall comply 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) that has an area of at least 250 square feet or greater as necessary to comply with equipment manufacturer specifications if the facility provides computerized tomography or magnetic resonance imaging services;
2. A film processing room, unless the facility exclusively uses digital technology;
3. A viewing area, unless the facility exclusively uses digital technology;
4. Film storage facilities for active, inactive, and unexposed film, unless the facility exclusively uses digital technology;
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. Separate toilet rooms with handwashing facilities for staff, visitors, and patients;
9. Handwashing facilities that are within each procedure room or, with respect to magnetic resonance imaging procedure rooms, located immediately outside the procedure room, as specified by the equipment manufacturer;
10. A control desk and reception area;
11. Storage facilities, including at least the following:
  - i. A room, closet, or cabinetry for storage of clean and sterile supplies; and
  - ii. A room for holding of soiled clinical material; and

12. A housekeeping room that contains a service sink and 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.
2. The requirements at N.J.A.C. 8:43A-3.6(a) and (b) regarding the availability and accessibility of the policy and procedure manual of the facility shall apply only to those policies and procedures which pertain to the services provided at the satellite facility.
3. The reporting of events as required by N.J.A.C. 8:43A-3.8 may be performed by the licensed facility with which the satellite is affiliated.
4. The information which N.J.A.C. 8:43A-3.9(a)1 and 2 require to be available in the facility may be kept at the licensed facility with which the satellite is affiliated rather than at the satellite itself.
5. The infection prevention and control program required by N.J.A.C. 8:43A-14.1 may be developed at the licensed facility with which the satellite is affiliated, but shall also be implemented at the satellite facility.
6. The written plan for a quality assurance program for patient care required by N.J.A.C. 8:43A-18.1(a) may be developed at the licensed facility with which the satellite is affiliated, but shall also be implemented at the satellite facility.

### **8:43A-27.2 On-site inspection**

An on-site inspection of the construction of the physical plant shall be made by representatives of Health Facilities Construction Services to verify that the building has been constructed in accordance with the architectural plans approved by the Department. The Department may choose to accept an equivalent inspection by a local agency in lieu of an inspection by representatives of Health Facilities Construction Services.

### **8:43A-27.3 Appointment of administrator**

The facility shall appoint an administrator of the satellite who shall be accountable to the governing authority. The administrator of the satellite may be the same person as

the administrator of the licensed facility with which the satellite is affiliated. The administrator of the satellite, or an alternate who shall be designated in writing to act in the absence of the administrator, shall be available in the satellite facility during its hours of operation.

**8:43A-27.4 Patient care policies**

All patient care policies and procedures which pertain to the services provided at the satellite facility shall be available in the satellite facility.

**8:43A-27.5 Medical records**

(a) Original medical records or components of medical records shall remain on the premises of the satellite or the licensed facility with which the satellite is affiliated 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.

(b) The satellite facility shall develop and implement a system for the establishment and maintenance of medical records for patients who come to the satellite facility on an unscheduled basis.

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## **SUBCHAPTER 28. BIRTH CENTERS**

### **8:43A-28.1 Additional requirements**

(a) A birth center shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter.

1. A birth center need not comply with N.J.A.C. 8:43A-7.2 through 7.4 and 8.2 and 8.3 for the purpose of licensure.

(b) No hospital, health care facility or other health care provider shall advertise or claim itself to be a "birth center" unless separately licensed as a birth center under this chapter.

### **8:43A-28.2 Service restrictions**

(a) Surgical procedures provided in the birth center shall be limited to those normally performed during and after uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or cesarean sections.

(b) Labor shall not be induced, inhibited, stimulated or augmented with pharmacological agents.

(c) General or conduction anesthesia shall not be administered at the birth center.

(d) The birth center is generally exempt from complying with requirements for anesthesia services at N.J.A.C. 8:43A-12. If anesthetic agents are administered for the purpose of creating conscious sedation, the birth center shall comply with the rules at N.J.A.C. 8:43A-12 which pertains to conscious sedation. Minor conduction blocks and local anesthesia may be administered by a certified nurse midwife in accordance with the scope of practice rules of the Board of Medical Examiners at N.J.A.C. 13:35-2A.4 and those personnel enumerated at N.J.A.C. 8:43A-12.3(k). The birth center shall establish and implement policies and procedures which address the administration of minor conduction blocks and local anesthesia.

(e) All mothers and infants shall be discharged or transferred within 24 hours from the time of the infant's birth. If it becomes necessary to retain a mother and/or infant beyond the 24-hour period, the birth center may do so only if it has been documented in the medical record that the mother and infant were expected to be discharged within 24 hours from the time of the infant's birth.

### **8:43A-28.3 Structural organization**

(a) The birth center shall be a formal member of a Maternal and Child Health Consortium and shall have been designated as a community perinatal center- birthing center by the Department of Health, in accordance with N.J.A.C. 8:33C.

(b) The birth center shall demonstrate a formal agreement with an affiliated community perinatal center, as defined at N.J.A.C. 8:43A-1.3, located within 20 minutes transport time for medical care of a woman or an infant when complications arise during the antepartum, intrapartum, postpartum or newborn period.

#### **8:43A-28.4 Designation of the clinical director**

The governing authority shall designate either an obstetrician in accordance with N.J.A.C. 8:43A-1.17 or a certified nurse midwife to serve as clinical director. The clinical director shall designate, in writing, an obstetrician or a certified nurse midwife to act in the absence of the clinical director. The clinical director, or his or her designee, shall be available to the facility at all times.

#### **8:43A-28.5 Clinical director's responsibilities**

(a) The clinical director shall be responsible for the direction, provision, and quality of clinical 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. All policies and procedures shall be reviewed at least annually;
2. Assisting in developing and maintaining written job descriptions for the clinical staff and assigning duties based upon education, training, competencies and job descriptions;
3. Participating in staff orientation and staff education activities;
4. Approving the contents, locations, and frequency of checking contents, including expiration dates, of emergency kits or carts, equipment, and supplies, and assigning responsibility for these checks;
5. Developing specifications for verbal orders, including who may give verbal orders, who may receive them, and how soon they must be verified or countersigned in writing; and
6. Establishing a system for completion of entries in the patient medical record.

#### **8:43A-28.6 Physician consultation**

(a) The birth center shall have a formal consultative relationship with an obstetrician. He or she shall be responsible for the quality of medical care provided, shall approve the birth center's admission criteria and all policies, procedures and protocols related to the medical management of care, and shall be available for consultation and referral.

(b) The birth center shall have a formal consultative relationship with an obstetrician for the purpose of clinical emergencies who has obstetrical privileges that include admission and care of maternity patients at the affiliated community perinatal center. The clinical director of the birth center may fulfill N.J.A.C. 8:43A-28.6(a) and (b), if he or she is an obstetrician.

(c) The birth center shall have a written agreement for services of a pediatrician or group of pediatricians with admitting privileges at the affiliated community perinatal center. This agreement shall ensure that a pediatrician is available at all times.

(d) Any certified nurse midwife practicing in the birth center shall have a written agreement with one or more obstetricians as required by the New Jersey State Board of Medical Examiners rules at N.J.A.C. 13:35-2A.3.

#### **8:43A-28.7 Additional policies and procedures**

(a) There shall be written policies and procedures for the prenatal, intrapartal and postpartal care of each patient. The policies and procedures shall be reviewed annually and revised as needed.

(b) The discharge protocol shall include assurance that, within 48 hours after discharge, each patient is called by a designated individual to determine the status of the patient and her newborn. A referral to a home health agency shall be made if clinically indicated.

(c) The birth center shall have a written protocol that sets forth the process to be followed in completing and filing all vital records with the local registrar who has jurisdiction over the municipality where the birth center is located.

(d) The birth center shall have a written protocol to be followed in completing and reporting all newborn screening tests to the Department of Health.

#### **8:43A-28.8 Additional patient care services**

(a) A certified nurse-midwife and/or physician shall perform an initial physical assessment of the patient and an evaluation of the patient's medical and emotional needs.

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

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

1. Urinalysis for glucose and protein;
  2. Hemoglobin and hematocrit repeated at 28 weeks;
  3. Sickle cells preparation (when appropriate);
  4. Rh factor and blood typing;
  5. Serological test for syphilis at the first prenatal visit, and in the last trimester of pregnancy or at delivery. If the patient is exposed to an infected partner, a serological test for syphilis shall be performed no sooner than three weeks after exposure;
  6. Papanicolaou smear at the first prenatal visit if not documented within the previous six months;
  7. Tuberculin test with indicated follow-up if in close contact with a diagnosed case of tuberculosis or from a high-incidence area so designated by the Department;
  8. Rubella titer. If this is negative, rubella vaccine with appropriate counseling regarding timing of future pregnancies shall be offered to the patient after delivery and prior to discharge from the birth center;
  9. One hour glucose tolerance test at 28 weeks gestation, if indicated by risk factors;
  10. Maternal serum alpha-fetoprotein testing offered at 15 to 20 weeks; and
  11. Hepatitis B virus screen with appropriate follow-up.
- (d) Each patient shall be individually counseled about her progress in pregnancy by a certified nurse-midwife, physician, or a registered professional nurse at every visit, and a progress note shall be recorded in the patient's medical record.
- (e) Each patient shall be examined at least once a month during the first seven months of gestation. Thereafter, the patient shall be seen every two weeks until 36 weeks and once a week thereafter. The examination shall be performed by either a certified nurse midwife or a physician.
- (f) The results of all tests performed during patient examinations shall be documented in the patient's medical record including at a minimum: blood pressure, weight, dipstick urine analysis for glucose and protein, uterine growth, fetal heart rate, abdominal inspection and palpation, any unusual symptoms reported by the patient, and any physical evidence of abnormality. Evaluation of nutritional status and breast and pelvic examinations shall be documented on a regular basis. The medical record shall

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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:

"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.

**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.



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**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 of Radiology or the American Osteopathic Board of Radiology in radiation oncology since 1976 or actively engaged in the process for certification by the American Board of Radiology or the American Osteopathic Board of Radiology.

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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.

i. 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.

ii. If the applicant fails to maintain good standing with that Board, the waiver shall automatically become null and void.

iii. 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 Cobalt60 units and other energy units are calibrated and used properly.

(e) For the purposes of this subchapter, qualified radiological physicists means one who:

1. 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
2. Does not meet the criteria in (e)1 above, but whose petition for recognition as a "qualified radiological physicist," as defined at N.J.A.C. 7:28-14.2, has been granted by the Commission on Radiation Protection.

(f) To obtain recognition as a "qualified radiological physicist" within the meaning of (e)2 above, the individual shall submit a written petition to the Commission on Radiation Protection that contains sufficient information about the individual's educational, professional, clinical, technical, employment and/or any other relevant experience, and shall adhere to such other procedures and requirements that the Commission may prescribe.

1. 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 physicists 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 single-unit facilities shall have dual photon energy equipment with electron capability.
- (d) 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.

#### **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 and existing radiation oncology facilities shall have and maintain accreditation by the American College of Radiology or the American College of Radiation Oncology.
- (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.

#### **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**

### **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, P.O. 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 -11 and 13 - 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 these rules, 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**

(a) If a licensing applicant believes that certain requirements of this chapter do not apply to the service proposed, then the applicant may request a waiver from those specific standards by following the process outlined at N.J.A.C. 8:43A-2.9.

(b) Waiver forms are available from the Office of Certificate of Need and Healthcare Facility Licensure.

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**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