N.J.A.C. TITLE 8

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

AUTHORITY

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

Effective Date: July 22, 2005 Readoption
Effective Date: September 6, 2005 Amendments, New Rules
Expiration Date: July 22, 2010

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

HOSPITAL LICENSING STANDARDS

TABLE OF CONTENTS

HOSPITAL LICENSING STANDARDS

TABLE OF CONTENTS

(Continued)

HOSPITAL LICENSING STANDARDS

Updated Information

Some of the contact information listed in these standards for the Department of Health and Senior Services and the Department of Community Affairs has changed. The correct information is noted below.

1) Questions regarding hospital inspections and complaints may be addressed to:

    Acute Care Survey Program
    New Jersey Department of Health and Senior Services
    P.O. Box 360
    Trenton, New Jersey 08625-0360
    Telephone: 609-292-9900

2) Questions regarding hospital licensing, or the Certificate of Need process, and requests for applications may be directed to:

    Director,
    Certificate of Need and Acute Care Licensure Program
    New Jersey Department of Health & Senior Services
    P.O. Box 360
    Trenton, New Jersey 08625-0360
    Telephone: 609-292-6552 or 292-7228

3) Questions concerning review of architectural plans and approval of construction for a health care facility shall be addressed to:

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

SUBCHAPTER 1. GENERAL PROVISIONS

8:43G-1.1 Scope and purpose

(a) These rules and standards apply to each licensed general or special hospital facility. They are intended for use in State surveys of the hospitals and any ensuing enforcement actions. They are also designed to be useful to consumers and providers as a mechanism for privately assessing the quality of care provided in any acute care hospital.

(b) This chapter contains rules intended to assure the high quality of care delivered in hospital facilities throughout New Jersey. Components of quality care addressed by these rules and standards include access to care, continuity of care, comprehensiveness of care, coordination of services, humaneness of treatment, conservatism in intervention, safety of environment, professionalism of caregivers, and participation in useful studies.

8:43G-1.2 Definitions

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

“All payer case mix index” (CMI) means a specific hospital’s average charge per case divided by the Statewide average charge per case for a given year using the most recent complete data set available to the Department.

“Clinical practitioner” means a physician, dentist, podiatrist certified nurse midwife, physician assistant, or nurse practitioner operating within his/her scope of practice.

"Hospital" means an institution, whether operated for profit or not, whether maintained, supervised or controlled by an agency of the government of the State or any county or municipality or not, which maintains and operates facilities for the diagnosis, treatment or care of two or more non-related individuals suffering from illness, injury or deformity and where emergency, out-patient, surgical, obstetrical, convalescent or other medical and nursing care is rendered for periods exceeding 24 hours.

"Hospital-based off-site ambulatory care service facility" means an ambulatory care service facility which has met the criteria as set forth in N.J.A.C. 8:43G-2.11(c) to be classified as same and which has applied for and received a license authorizing the facility to operate as a hospital-based off-site ambulatory care service facility.

"Hospitalization" means the admission and care of any person for a continuous period, longer than 24 hours, for the purpose of diagnosis and/or treatment bearing on the physical or mental health of such persons.

"Licensee" means the corporation, association, partnership or person authorized by the Department of Health to operate an institution and on whom rests the responsibility for maintaining acceptable standards in all areas of operation.

"Patient" means a person who receives a health care service from a provider.

8:43G-1.3 Classification of institutions

(a) Hospitals shall be classified generally as:

1. Private, non-profit, which shall include any hospital owned and operated by a corporation, association, religious or other organization, no part of the net earnings of which is applied, or may lawfully be applied, to the benefit of any private shareholder or person;

2. Private proprietary or profit, which shall include any hospital owned and operated by a person, partnership or corporation, the net proceeds of which are subject to distribution for the benefit of such person, corporation or shareholders; and

3. Public hospital, which shall include any institution maintained, supervised or controlled by an agency of the government of the State or any county or municipality that provides diagnostic and/or treatment services for the care of two or more non-related individuals suffering from illness, injury or deformity.

(b) Hospitals shall be further classified as:

1. General hospital, which shall include any hospital which maintains and operates organized facilities and services for the diagnosis, treatment or care of persons suffering from acute illness, injury or deformity and in which all diagnosis, treatment and care are administered by or performed under the direction of persons licensed to practice medicine or osteopathy in the State of New Jersey;

2. Special hospitals which shall include any hospital which assures provision of comprehensive specialized diagnosis, care, treatment and rehabilitation where applicable on an inpatient basis for one or more specific categories and for a hospital that provides long term acute care through a broad spectrum of clinical care services for acutely ill/medically complex patients requiring, on average, a 25-day or greater length of stay. Special hospitals do not include hospitals or hospital units providing comprehensive rehabilitation services and licensed in accordance with the provisions of N.J.A.C. 8:43H. Special hospitals providing long term acute care services shall be further classified as follows:

i. Long term acute care hospital-within -a-hospital means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 CFR Part 412 et al. that occupies space in a building also used by another hospital and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38.

ii. Long term acute care hospital-freestanding means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 CFR Part 412 et al. that is a physically separate self-contained facility and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38; and

3. Psychiatric hospital, which shall include any hospital which assures provision of comprehensive specialized diagnosis, care, treatment and rehabilitation where applicable on an in-patient basis for patients with primary psychiatric diagnoses.

8:43G-1.4 Information and complaint procedure

(a) Questions regarding hospital licensure may be addressed to the Certificate of Need and Acute Care Licensure Program at the following address:

New Jersey State Department of Health and Senior Services
Division of Health Care Quality and Oversight
P.O. Box 360
Trenton, NJ 08625-0360

Current address and contact information can be obtained at the Department's website address: www.state.nj.us/health/hcsa/hcsaforms.html

(b) To make a complaint about any New Jersey licensed health care facility, call: 1-800-792-9770 (toll-free hotline)

SUBCHAPTER 2. LICENSURE PROCEDURE

8:43G-2.1 Certificate of Need

(a) Where, in accordance with N.J.S.A. 26:2H-1 et seq., as amended, a Certificate of Need is required, a hospital shall not be instituted, constructed, expanded or licensed to operate except upon application for and receipt of a Certificate of Need issued by the Commissioner of the Department of Health and Senior Services.

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

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

(c) The hospital shall implement all conditions imposed by the Commissioner as specified in Certificate of Need approval letters. Failure to implement the conditions may result in the imposition of enforcement sanctions in accordance with N.J.S.A. 26:2H-13 and 14.

8:43G-2.2 Application for licensure

(a) Where applicable, following receipt of a Certificate of Need as a hospital, any person, organization, or corporation desiring to operate a hospital shall make application to the Commissioner for a license on forms prescribed by the Department. Such forms may be obtained from the Department's website address www.state.nj.us/health/hcsa/hcsaforms.html or from:

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

(b) The Department shall charge a nonrefundable fee of $10,000 for the filing of an application for licensure and each annual renewal of a general acute care, special, or psychiatric hospital. These fees shall not exceed the maximum caps as set forth at N.J.S.A. 26:2H-12, as may be amended from time to time.

(c) The Department shall charge a nonrefundable fee of $3,000 for the filing of an application to add services to an existing general acute care, special, or psychiatric hospital.

(d) The Department shall charge a nonrefundable fee of $375.00 for the filing of an application to reduce services at an existing general acute care, special or psychiatric hospital.

(e) The Department shall charge a nonrefundable fee of $1,500 for the filing of an application for the relocation of a general acute care, special or psychiatric hospital.

(f) The Department shall charge a nonrefundable fee of $1,500 for the filing of an application for the transfer of ownership of a general acute care, special or psychiatric hospital.

(g) Each general acute care, special, and psychiatric hospital shall be assessed a biennial inspection fee of $5,000. 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.

(h) If a hospital operates a service that is subject to separate licensing regulation, for example, a long-term care or comprehensive rehabilitation facility, the Department shall charge an additional licensing fee for that service, as set forth in the applicable rules.

(i) All applicants shall demonstrate that they have the capacity to operate a hospital in accordance with the rules in this chapter. An application for a license or change in service may be denied if the applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances, rules and bylaws, and standards or 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. Any evidence of licensure violations representing serious risk of harm to patients may be considered by the Department, as well as any record of criminal convictions representing a risk of harm to the safety or welfare of patients.

(j) Any applicant denied a license to operate a facility shall have the right to a fair hearing in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedures Rules, N.J.A.C. 1:1.

8:43G-2.3 Newly constructed or expanded facilities

(a) The licensure application for a newly constructed or expanded hospital pursuant to N.J.A.C. 8:43G-2.2 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 construction plan approval by:

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

(b) An on-site inspection of the construction of the physical plant shall be made at the Department's discretion by representatives of the Acute Care Survey Program to verify that the building has been constructed in accordance with the final architectural plans approved by the Department.

(c) Any health care facility which intends to undertake any alteration, renovation, or new construction of the physical plant, whether a Certificate of Need is required or not, shall submit plans to the Health Plan Review Program of the Department of Community Affairs for review and approval prior to the initiation of any work.

8:43G-2.4 Surveys and temporary license

(a) When the written application for licensure pursuant to N.J.A.C. 8:43G-2.2 is approved and the building is ready for occupancy, a survey of the facility by representatives of the Division of Health Care Quality and Oversight of the Department shall be conducted at the Department's discretion to determine if the facility meets the standards set forth in this chapter.

1. Representatives of the Division of Health Care Quality and Oversight of the Department shall discuss the findings of the survey, including any deficiencies found, with representatives of the hospital facility.

2. The hospital facility shall notify the Division of Health Care Quality and Oversight of the Department in writing when the deficiencies, if any, have been corrected. Following review of the hospital facility's report, the Division of Health Care Quality and Oversight's Acute Care Survey Program may schedule one or more surveys of the facility prior to occupancy.

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

1. An office conference for review of the conditions for licensure and operation has taken place between the Licensing and Certification Program and representatives of the hospital facility, who have been advised that the purpose of the temporary license is to allow the Department to determine the hospital's compliance with N.J.S.A. 26:2H-1 et seq., and amendments thereto, and the rules pursuant thereto;

2. Written approvals are on file with the Department from the local zoning, fire, health, and building authorities;

3. Written approvals of the water supply and sewage disposal system from local officials are on file with the Department for any water supply or sewage disposal system not connected to an approved municipal system; and

4. Survey(s) by representatives of the Department indicate that the hospital meets the mandatory standards set forth in this chapter.

(c) No hospital facility shall accept patients in any new service, unit, or facility until the hospital has a written approval and/or license issued by the Certificate of Need and Acute Care Licensure Program of the Department.

(d) The hospital shall accept only that number of patients for which it is approved and/or licensed.

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

(f) A temporary license shall be issued to the operator of a hospital facility for a period of six months and shall be renewed as determined by the Department.

1. The temporary license shall be conspicuously posted in the hospital facility.

2. The temporary license shall not be assignable or transferable and 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.

8:43G-2.5 Full license

(a) A full license shall be issued to the operator on expiration of the temporary license, if the surveys by the Department have determined that the health care facility is operated as required by N.J.S.A. 26:2H-1 et seq., and amendments thereto, 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 in accordance with (a) above.

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

(d) The license shall not be assignable or transferable and shall be immediately void if the hospital ceases to operate, if its ownership changes, or if it is relocated to a different site. A representative of the hospital shall notify the Department of any change in the ownership form or controlling interests affecting hospital governance. The Department shall determine whether a certificate of need or licensing application must be completed prior to the implementation of any ownership changes based upon the information filed and the criteria within N.J.A.C. 8:33-3.3.

(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.

1. The facility shall receive a request for renewal fee 30 days prior to expiration of the license. A renewal license shall not be issued unless the licensure fee is received by the Department.

2. The license may not be renewed if Departmental rules, regulations and/or requirements are not met.

8:43G2.6 Revocation or suspension of license

(a) The Department is authorized to suspend or revoke a license issued pursuant to this subchapter, order closure of a service or unit within the hospital, or impose a money penalty on any of the following grounds:

1. Violation of any provisions of N.J.S.A. 26:2H-1 et seq. or any rules and regulations issued pursuant thereto;

2. Permitting, aiding or abetting the commission of any illegal act in said facility; and/or

3. Conducting practices contrary to accepted procedures and detrimental to the welfare of the patient.

8:43G-2.7 Surrender of license

At least 30 days prior to voluntary surrender of its license where approved by Certificate of Need, or as directed under an order of revocation, refusal to renew, or suspension of license, a facility must directly notify each patient and the patient's physician concerned of the intended closure. The license shall be returned to the Licensing and Certification Program of the Department within seven calendar days from voluntary surrender, order of revocation, expiration, or suspension of license, whichever is applicable.

8:43G-2.8 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 amendments thereto, and the standards in this chapter, waive sections of this chapter if, in his or her opinion, such waiver would not endanger the life, safety, or health of the patient or public.

(b) A facility seeking a waiver of the standards in this chapter shall apply in writing to the Director of the Licensing and Certification Program of the Department.

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

1. The nature of the waiver requested;

2. The specific standards for which a waiver is requested;

3. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility upon full compliance;

4. An alternative proposal which would ensure patient safety; and

5. Documentation to support the waiver application.

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

8:43G-2.9 Action against licensee

(a) Violations of this chapter may result in action by the New Jersey State Department of Health to impose a fine, pursuant to N.J.S.A. 26:2H-1 et seq., cease admissions to a facility, order removal of patients from a facility, revoke or suspend a license, and/or impose other lawful remedies.

(b) If the Department determines that operational or safety deficiencies exist, it may require that all admissions to 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.

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

(d) Any licensee made subject to action by the Department for suspension or revocation of license or who is assessed a fine under terms of this section shall have the right to a fair hearing in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedures Rules, N.J.A.C. 1:1.

8:43G-2.10 Information not to be disclosed

(a) Information received by the Department of Health through inspection authorized by N.J.S.A. 26:2H-1 et seq. shall not be disclosed to the public in such a way as to indicate the names of the specific patients or hospital employees to whom the information pertains. The Department shall forward inspection reports to the hospital facility at least 30 days prior to public disclosure. In all cases in which the hospital comments on the inspection report, the hospital comments and the inspection report shall be released simultaneously by the Department. In cases in which the New Jersey State Commissioner of Health determines that the protection of public health and safety necessitates immediate public disclosure of information, inspection reports may be disclosed immediately.

(b) Nothing contained herein shall be construed to interfere with existing legislation or the established rights and privileges of the public prosecutor and litigants having access to hospital records, nor shall determinations herein be construed to interfere in any way with the orderly legal process of obtaining access to such records.

8:43G-2.11 Hospital satellite facilities and off-site ambulatory care service facilities

(a) A satellite hospital facility may be operated under the effective supervision of an existing hospital.

(b) Individual licenses shall not be required for separate hospital buildings and services located on the same or adjoining grounds, if these are operated under one management.

(c) All off-site ambulatory care service facilities (including mobile units) must be licensed to operate by the Department. A hospital may seek licensure and classification of off-site ambulatory care service facilities as either "free-standing" or "hospital-based" facilities. Both "free-standing" and "hospital-based" off-site ambulatory care service facilities shall be separately inspected and separately licensed in accordance with the provisions set forth at N.J.A.C. 8:43A, Standards for Licensure of Ambulatory Care Facilities. All off-site ambulatory care service facilities are presumed to be "free-standing." A hospital seeking licensure and classification of an off-site ambulatory care service facility as "hospital-based" shall so indicate on the licensure application and shall provide documentation of the following:

1. The hospital-based off-site ambulatory care service facility is integrated with and subordinate and accountable to the hospital. Services provided at the off-site location are clinically integrated with other departments of the hospital and staff members are employees of the hospital. Where applicable, credentialing of hospital-based ambulatory care service facility staff is performed by the hospital credentialing committee. Where applicable, the hospital-based ambulatory care service facility is required to comply with the provisions set forth at N.J.A.C. 8:43G-4.1, Patient rights.

2. The hospital-based ambulatory care service facility administrator is subordinate to and reports to an identified administrator at the hospital. The hospital Chief Medical Officer (or similar official) is also responsible for the medical direction of the hospital-based ambulatory care service facility.

3. If the hospital is accredited, the hospital-based ambulatory care service facility is included in the accreditation and the accrediting body recognizes the hospital-based ambulatory care service facility as part of the hospital.

4. The hospital-based off-site ambulatory care service facility is operated under common ownership and control and by the same governing body as the hospital. The factors considered in evaluating this criterion are one or more of the following:

i. The hospital-based ambulatory care service facility and the hospital are subject to common by-laws and operating decisions of the governing body;

ii. Final responsibility for administrative decisions, personnel actions and approval of hospital-based ambulatory care service facility medical staff appointments rests with the hospital;

iii. The hospital-based ambulatory care service facility functions as a department of the hospital; and/or

iv. The hospital has written policies, procedures and protocol applicable to the hospital-based ambulatory care service facility, assuring that the requirements of this section are followed.

5. The director of the hospital-based ambulatory care service facility must function under the day-to-day supervision of the hospital. The factors considered in evaluating this criterion are one or more of the following:

i. The hospital-based ambulatory care service facility director (or the individual responsible for the day-to-day operation of the hospital-based ambulatory care service facility) reports daily and is accountable to the chief executive officer of the hospital and also reports to the hospital governing body through the chief executive officer;

ii. Medical records, billing, laundry, housekeeping, purchasing and all other administrative functions of the hospital-based ambulatory care service facility are integrated with those of the hospital; and/or

iii. The hospital has written policies, procedures and protocol applicable to the hospital-based ambulatory care service facility, assuring that the requirements of this section are followed.

6. All hospital-based ambulatory care service facility clinical services are integrated with those of the hospital. The factors considered in evaluating this criterion are one or more of the following:

i. Hospital-based ambulatory care service facility professional staff have clinical privileges in the hospital;

ii. Where applicable, the hospital-based ambulatory care service facility medical director reports to the chief medical officer (or similar official) of the hospital on a daily basis;

iii. All hospital medical staff and other professional committees are responsible for all medical activities at the hospital-based ambulatory care service facility;

iv. Medical records for patients treated in the hospital-based ambulatory care service facility are integrated into the unified records system of the hospital;

v. Patients treated at the hospital-based ambulatory care service facility are considered patients of the hospital and have full access to all hospital services;

vi. Patient services provided at the hospital-based ambulatory care service facility are integrated with corresponding hospital inpatient and/or outpatient services, as appropriate; and/or

vii. The hospital has written policies, procedures and protocol applicable to the hospital-based ambulatory care service facility, assuring that the requirements of this section are followed.

7. The hospital-based ambulatory care service facility is held out to the public as part of the hospital such that patients know they are entering the hospital and will be billed accordingly.

8. The hospital and the hospital-based ambulatory care service facility are financially integrated. The factors considered in evaluating this criterion are one or more of the following:

i. The hospital and the hospital-based ambulatory care service facility have a written agreement for the sharing of income and expenses; and/or

ii. The hospital-based ambulatory care service facility reports its costs, including total revenues and total expenses, as part of the hospital's audited financial statements and uses the same accounting system for the same cost reporting period as the hospital.

9. The hospital-based ambulatory care service facility accepts and provides care to patients in accordance with the provisions as set forth in N.J.A.C. 8:43G-5.2(c) and, accordingly, shall not deny admission to patients on the basis of their inability to pay.

8:43G-2.12 Mandatory services in general and psychiatric hospitals

(a) All general hospitals applying for licensure shall provide the following professional departments, services, facilities, and functions:

1. Administration;

2. Anesthesia Department;

3. Blood Bank;

4. Central Supply;

5. Clinical and Pathological Laboratories;

6. Dietary Services;

7. Discharge Planning;

8. Emergency Department;

9. Employee and Occupational Health;

10. Electrocardiogram Laboratory;

11. Housekeeping and Laundry Services;

12. Infection Control and Sanitation;

13. Medical Library;

14. Medical Records;

15. Medical/Surgical Service;

16. Medical Staff;

17. Morgue and Autopsy Facilities;

18. Nursing Service;

19. Out-Patient and Preventive Services, including regularly scheduled clinic services for medically indigent patients;

20. Pharmacy Department;

21. Physical and Occupational Therapy;

22. Physical Plant and Maintenance;

23. Post Anesthesia Care Unit;

24. Quality Assurance;

25. Radiology;

26. Respiratory Therapy Services; and

27. Social Work Department.

(b) All psychiatric hospitals applying for licensure shall provide the following professional departments, services, facilities, or functions:

1. Administration;
2. Anesthesia department (only if electro-convulsive therapy is provided);
3. Dietary services:
4. Discharge planning;
5. Emergency department (8:43G-12.1 only);
6. Employee and occupational health;
7. Housekeeping and laundry services;
8. Infection control and sanitation;
9. Medical records;
10. Medical staff;
11. Post mortem services (8:43G-25.1 and 25.3(b) through (d) only);
12. Nursing service;
13. Patient rights;
14. Pharmacy services;
15. Rehabilitation therapy;
16. Physical plant and maintenance;
17. Psychiatric services;
18. Quality assurance; and
19. Social services.

8:43G-2.13 Child abuse and neglect

(a) The facility shall establish and implement written policies and procedures, reviewed by the Department and revised as required by the Department, for reporting all diagnosed and/or suspected cases of child abuse and/or neglect in compliance with N.J.S.A. 9:6-1 et seq.

(b) The facility shall have in effect written policies and procedures reviewed by the Department and revised as required by the Department to include, but not be limited to, the following:

1. 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 on a 24-hour basis, recording the notification to the Division of Youth and Family Services on the medical record, and serving as a liaison between the facility and the Division of Youth and Family Services;

2. The development of written protocols for the identification and treatment of abused and/or neglected children for the emergency room, clinic, and pediatrics, where such services exist, for admission and/or transfer to another facility and for protective custody through the use of hospital hold in accordance with N.J.S.A. 9:6-8.16; and

3. The provision 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 and regarding the facility's policies and procedures on at least an annual basis.

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 or from the Office of Program Support, Division of Youth and Family Services, Trenton, New Jersey 08625.

SUBCHAPTER 3. (RESERVED)

SUBCHAPTER 4. PATIENT RIGHTS

8:43G-4.1 Patient rights

(a) Every New Jersey hospital patient shall have the following rights, none of which shall be abridged by the hospital or any of its staff. The hospital administrator shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights. These rights shall include at least the following:

1. To receive the care and health services that the hospital is required to provide under N.J.S.A. 26:1-1 et seq. and rules adopted by the Department of Health and Senior Services to implement this law;

2. To treatment and medical services without discrimination based on race, age, religion, national origin, sex, sexual preferences, handicap, diagnosis, ability to pay, or source of payment;

3. To retain and exercise to the fullest extent possible all the constitutional, civil, and legal rights to which the patient is entitled by law;

4. To be informed of the names and functions of all physicians and other health care professionals who are providing direct care to the patient. These people shall identify themselves by introduction or by wearing a name tag;

5. To receive, as soon as possible, the services of a translator or interpreter to facilitate communication between the patient and the hospital's health care personnel;

6. 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 condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives. 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 his or her next of kin or guardian and documented in the patient's medical record;

7. To give informed, written consent prior to the start of specified nonemergency procedures or treatments only after a physician or clinical practitioner has explained - in terms that the patient understands - specific details about the recommended procedure or treatment, the risks involved, the possible duration of incapacitation, and any reasonable medical alternatives for care and treatment. The procedures requiring informed, written consent shall be specified in the hospital's policies and procedures. If the patient is incapable of giving informed, written consent, consent shall be sought from the patient's next of kin or guardian or through an advance directive, to the extent authorized by law. If the patient does not given written consent, a physician or clinical practitioner shall enter an explanation in the patient's medical record;

8. To refuse medication and treatment to the extent permitted by law and to be informed of the medical consequences of this act;

9. To be included in experimental research only when he or she gives informed, written consent to such participation, or when a guardian provides such consent for an incompetent

patient in accordance with law and regulation. The patient may refuse to participate in experimental research, including the investigations of new drugs and medical devices;

10. To be informed if the hospital 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 may refuse to allow their participation in the patient's treatment;

11. To be informed of the hospital's policies and procedures regarding life-saving methods and the use or withdrawal of life-support mechanisms. Such policies and procedures shall be made available promptly in written format to the patient, his or her family or guardian, and to the public, upon request;

12. To be informed by the attending physician and other providers of health care services about any continuing health care requirements after the patient's discharge from the hospital. The patient shall also have the right to receive assistance from the physician and appropriate hospital staff in arranging for required follow-up care after discharge;

13. To receive sufficient time before discharge to have arrangements made for health care needs after hospitalization;

14. To be informed by the hospital about any discharge appeal process to which the patient is entitled by law;

15. To be transferred to another facility only for one of the following reasons, with the reason recorded in the patient's medical record:

i. The transferring hospital is unable to provide the type or level of medical care appropriate for the patient's needs. The hospital shall make an immediate effort to notify the patient's primary care physician and the next of kin, and document that the notifications were received; or

ii. The transfer is requested by the patient, or by the patient's next of kin or guardian when the patient is mentally incapacitated or incompetent;

16. To receive from a physician an explanation of the reasons for transferring the patient to another facility, information about alternatives to the transfer, verification of acceptance from the receiving facility, and assurance that the movement associated with the transfer will not subject the patient to substantial, unnecessary risk of deterioration of his or her medical condition. This explanation of the transfer shall be given in advance to the patient, and/or to the patient's next of kin or guardian except in a life-threatening situation where immediate transfer is necessary;

17. To be treated with courtesy, consideration, and respect for the patient's dignity and individuality;

18. To freedom from physical and mental abuse;

19. To freedom from restraints, unless they are authorized by a physician for a limited period of time to protect the patient or others from injury;

20. To have physical privacy during medical treatment and personal hygiene functions, such as bathing and using the toilet, unless the patient needs assistance for his or her own safety. The patient's privacy shall also be respected during other health care procedures and when hospital personnel are discussing the patient;

21. To confidential treatment of information about the patient. Information in the patient's records shall not be released to anyone outside the hospital 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, a medical peer review, or the New Jersey State Department of Health. The hospital may release data about the patient for studies containing aggregated statistics when the patient's identity is masked;

22. To receive a copy of the hospital payment rates, regardless of source of payment. Upon request, the patient or responsible party shall be provided with an itemized bill and an explanation of the charges if there are further questions. The patient or responsible party has a right to appeal the charges. The hospital shall provide the patient or responsible party with an explanation of procedures to follow in making such an appeal;

23. To be advised in writing of the hospital rules and regulations that apply to the conduct of patients and visitors;

24. To have prompt access to the information contained in the patient's medical record, unless a physician prohibits such access as detrimental to the patient's health, and explains the reason in the medical record. In that instance, the patient's next of kin or guardian shall have a right to see the record. This right continues after the patient is discharged from the hospital for as long as the hospital has a copy of the record;

25. To obtain a copy of the patient's medical record, at a reasonable fee, within 30 days of a written request to the hospital. If access 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;

26. To have access to individual storage space in the patient's room for the patient's private use. If the patient is unable to assume responsibility for his or her personal items, there shall be a system in place to safeguard the patient's personal property until the patient or next of kin is able to assume responsibility for these items;

27. To be given a summary of these patient rights, as approved by the New Jersey State Department of Health, and any additional policies and procedures established by the hospital involving patient rights and responsibilities. This summary shall also include the name and phone number of the hospital staff member to whom patients can complain about possible patient rights violations. This summary shall be provided in the patient's native language if 10 percent or more of the population in the hospital's service area speak that language. In addition, a summary of these patient rights, as approved by the New Jersey State Department of Health, shall be posted conspicuously in the patient's room and in public places throughout the hospital. Complete copies of this subchapter shall be available at nurse stations and other patient care registration areas in the hospital for review by patients and their families or guardians;

28. To present his or her grievances to the hospital staff member designated by the hospital to respond to questions or grievances about patient rights and to receive an answer to those grievances within a reasonable period of time. The hospital is required to provide each patient or guardian with the names, addresses, and telephone numbers of the government agencies to which the patient can complain and ask questions, including the New Jersey Department of Health Complaint Hotline at 1-800-792-9770. This information shall also be posted conspicuously in public places throughout the hospital;

29. To be assisted in obtaining public assistance and the private health care benefits to which the patient may be entitled. This includes being advised that they are indigent or lack the ability to pay and that they may be eligible for coverage, and receiving the information and other assistance needed to qualify and file for benefits or reimbursement;

30. To contract directly with a New Jersey licensed registered professional nurse of the patient's choosing for private professional nursing care during his or her hospitalization. A registered professional nurse so contracted shall adhere to hospital policies and procedures in regard to treatment protocols, and policies and procedures so long as these requirements are the same for private duty and regularly employed nurses. The hospital, upon request, shall provide the patient or designee with a list of local non-profit professional nurses association registries that refer nurses for private professional nursing care; and

31. 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.

8:43G-4.2 (Reserved)

SUBCHAPTER 5. ADMINISTRATIVE AND HOSPITAL-WIDE SERVICES

8:43G-5.1 Administrative and hospital-wide structural organization

(a) There shall be an organizational chart of the hospital and each service that shows lines of authority, responsibility, and communication between and within services.

(b) The hospital shall have an established and functioning governing body responsible for establishing hospital-wide policy, adopting bylaws, maintaining quality of care, and providing institutional management and planning.

(c) The governing body shall designate an administrator or chief executive officer for the hospital and develop criteria used to evaluate the performance of the administrator or chief executive officer.

(d) The hospital shall advise the New Jersey State Department of Health, Division of Health Facilities Evaluation and Licensing, in writing within 15 days following any change in the designation of the administrator or chief executive officer of the hospital.

(e) The medical staff shall have the right of representation at governing body meetings.

(f) There shall be a formal mechanism for communication among the governing body, administration, and medical staff.

(g) Minutes of governing body meetings shall be recorded, signed, and retained in the hospital as a permanent record.

(h) The hospital shall have a multidisciplinary bioethics committee, and/or prognosis committee(s), or equivalent(s). The hospital shall assure participation by individuals with medical, nursing, legal, social work, and clergy backgrounds. The committee or committees shall have at least the following functions:

1. Participation in the formulation of hospital policy related to bio-ethical issues;

2. Participation in the formulation of hospital policy related to advance directives. Advance directive shall mean a written statement of the patient's instructions and directions for health care in the event of future decision making incapacity in accordance with the New Jersey Advance Directives for Health Care Act (P.L. 1991, c.201). An "advance directive" may include a proxy directive or an instruction directive, or both.

3. Participation in the resolution of patient-specific bioethical issues, and responsibility for conflict resolution concerning the patient's decision- making capacity and in the interpretation and application of advance directives. The committee may partially delegate responsibility for this function to any individual or individuals who are qualified by their backgrounds and/or experience to make clinical and ethical judgments; and

4. Providing a forum for patients, families, and staff to discuss and reach decisions on ethical concerns relating to patients.

(i) The hospital shall establish a mechanism for involving consumers in the formulation of hospital policy related to bio-ethical issues.

(j) The hospital shall provide periodic community education programs, individually or in coordination with other area facilities or organizations, that provide information to consumers regarding advance directives and their rights under New Jersey law to execute advance directives.

(k) The hospital shall establish policies and procedures for the declaration of death of patients in accordance with N.J.S.A. 26:6 and the New Jersey Declaration of Death Act (P.L. 1991, c.90). The policies and procedures shall accommodate a patient's religious beliefs with respect to declaration of death. Such policies shall also be in conformance with regulations and policies promulgated by the New Jersey Board of Medical Examiners which address declaration of death based on neurological criteria, including the qualifications of physicians authorized to declare death based on neurological criteria and the acceptable medical criteria, tests, and procedures which may be used.

(l) All hospitals are required to maintain an on-call list of appropriate primary care and sub-specialty physicians for all patients who require emergency department treatment or admission to the hospital for continuing care. All such patients being admitted to the hospital for continuing care shall be presumed to require routine care unless a clinical provider (physician, physician's assistant, advanced practice nurse, nurse practitioner, registered nurse) determines the patient's condition to be emergent. Routine and emergent cases shall be disposed as follows:

1. Consult requests designated as "routine" indicate that the requesting clinical provider wishes to present a patient to the on-call physician, but that the patient's condition does not require emergency consultation. The hospital shall have a by-law to determine the appropriate on-call physician response time to consult requests for routine cases.

2. Consult requests designated as "emergent" indicate that the requesting clinical provider wishes to present a patient to the on-call physician and that the patient's condition requires the on-call physician's prompt response. Since patient outcome in emergent cases may be directly related to care provided by the on-call physician, that physician shall respond by telephone within 20 minutes of receiving a call from hospital clinical staff. In addition, the treating physician present in the hospital and the on-call physician shall discuss and agree upon an appropriate in-person response time for the on-call physician. If the physicians are unable to reach an agreement as to an appropriate in-person response time for the on-call physician, then the opinion of the treating physician present in the hospital shall govern. However, with regard to patients aged 18 or under, the in-person response time shall not be longer than 60 minutes after the initial call to the on-call physician. The hospital shall note on the patient's medical record the events occurring during the patient's stay in the emergency department. The hospital shall monitor that information and the hospital quality improvement staff shall review that information at least annually.

8:43G-5.2 Administrative and hospital-wide policies and procedures

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

1. Policies on the admission of patients, transfer of patients to another facility, and discharge of patients;

2. Procedures for obtaining the patient's written informed consent for all medical treatment;

3. Delineation of the responsibilities of the medical staff, nursing, and other staff in contacting the patient's family in the event of death, elopement, or a serious change in condition;

4. Policies addressing bio-ethical issues affecting individual patients, including at least removal of life support systems, discontinuance or refusal of treatment, and designation not to resuscitate. In accordance with the New Jersey Advance Directives for Health Care Act (P.L. 1991, c.201), private, religiously-affiliated health care institutions which decline to participate in the withholding or withdrawing of specified life-sustaining measures shall comply with the following:

i. The hospital shall establish written policies defining circumstances in which it will decline to participate in the withholding or withdrawing of specified life-sustaining measures in accordance with the patient's advance directive;

ii. The hospital shall provide prompt notice to patients or their families or health care representatives of these policies prior to or upon admission, or as soon after admission as is practical; and

iii. The hospital shall implement a timely and respectful transfer of the individual to another institution who will implement the patient's advance directive;

5. Procedures to ensure that there is a routine inquiry made of each adult patient, upon admission to the hospital and at other appropriate times, concerning the existence and location of an advance directive (as required and defined in the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201). If the patient is incapable to respond to this inquiry, the hospital shall have procedures to request the information from the patient's family or in the absence of family, another individual with personal knowledge of the patient, if available and known to the hospital. The procedures must assure that the patient or family's response to this inquiry is documented in the medical record. Such procedures shall also define the role of hospital admissions, nursing, social service and other staff as well as the responsibilities of the attending physician;

6. Policies which identify circumstances in which an inquiry will be made of adult individuals receiving same day surgery, same day medical services, treatment in the emergency department or out-patient hemodialysis treatment regarding the existence and location of an advance directive;

7. Procedures to request and to take reasonable steps to promptly obtain a copy of currently executed advance directives from inpatients and other critically ill patients who are under treatment at the hospital. These shall be entered when received into the medical record of the patient. When there is a question of validity, procedures for promptly evaluating the validity of the advance directive must be established;

8. Procedures for promptly alerting physicians, nurses, and other professionals providing care to patients who have informed the hospital of the existence of an advance directive in instances where a copy is not immediately available for the medical record;

9. Policies for transfer of the responsibility for care of patients with advance directives in those instances where a health care professional declines as a matter of professional conscience to participate in withholding or withdrawing life-sustaining treatment. Such transfer shall assure that the patient's advance directive is implemented in accordance with their wishes within the hospital;

10. Means to provide each adult patient upon admission, or where the patient is unable to respond, family or other representative with a written statement of their rights under New Jersey law to make decisions concerning the right to refuse medical care and the right to formulate an advance directive. This statement of rights shall be issued by the Commissioner. Appropriate written information and materials on advance directives and the institution's written policies and procedures including the withdrawal or withholding of life-sustaining treatment shall be provided to each patient and others upon request. Such written information shall also be made available in any language which is spoken as the primary language by more than 10 percent of the population of the hospital's service area;

11. Procedures for referral of patients requesting assistance in executing an advance directive or additional information to either staff or community resource persons that can promptly advise and/or assist the patient during the inpatient stay; and

12. Policies to ensure application of the hospital's procedures for advance directives to patients who are receiving emergency room care for an urgent life-threatening situation.

(b) A patient shall be transferred to another hospital only for a valid medical reason, in order to comply with other applicable laws or Department rules, to comply with clearly expressed and documented patient choice, or in conformance with the New Jersey Advance Directives for Health Care Act.

The hospital's inability to care for the patient shall be considered a valid medical reason. The sending hospital shall receive approval from a physician and the receiving hospital before transferring the patient. Documentation for the transfer shall be sent with the patient, with a copy or summary maintained by the transferring hospital. This documentation shall include, at least:

1. The informed consent of the patient or responsible individual, in accordance with State law;

2. The reason for the transfer;

3. The signature of the physician who ordered the transfer;

4. The condition of the patient upon transfer;

5. Patient information collected by the sending hospital, as specified in N.J.A.C. 8:43G-15.2(e);

6. The name of the contact person at the receiving hospital; and

7. A copy of the patient's advance directive where available or notice that the individual has informed the sending hospital of the existence of an advance directive.

(c) The hospital shall not deny admission to patients on the basis of their inability to pay.

(d) Patients shall be discharged only on physician's orders or after signing a waiver that exempts the hospital and the physician from liability as a result of the patient's leaving the hospital against medical advice. Patient refusal to sign such a waiver shall be documented.

(e) The hospital shall have a patient identification system that is used for all patients in the hospital from the time of admission until the time the patient is released from the hospital.

(f) Upon arrival at a service location, an inpatient's treatment shall be initiated within 30 minutes. Following completion of treatment, the patient shall be returned to his or her hospital room within a reasonable length of time not to exceed 30 minutes.

(g) The hospital shall develop and implement a complaint procedure for patients, families, and other visitors. The procedure shall include, at least, a system for receiving complaints, a specified response time, assurance that complaints are referred appropriately for review, development of resolutions, and follow-up action.

(h) The hospital shall develop and implement a grievance procedure for all staff. The procedure shall include, at least, a system for receiving grievances, a specified response time, assurance that grievances are referred appropriately for review, development of resolutions, and follow-up action.

(i) There shall be written policies and procedures for personnel that are viewed annually, revised as needed, and implemented. They shall include at least:

1. A written job description for each category of personnel in the hospital and distribution of a copy to each newly hired employee;

2. Personnel policies in compliance with Federal requirements for Equal Employment Opportunity;

3. A system to ensure that written, job-relevant criteria are used in making evaluation, hiring, and promotion decisions;

4. A system to ensure that employees meet ongoing requirements for credentials; and

5. Written criteria for personnel actions that require disciplinary action.

(j) The hospital shall comply with all requirements of the professional licensing boards for reporting terminations, suspensions, revocation, or reduction of privileges for any health professionals licensed in the State of New Jersey.

(k) Personnel records shall be confidential material, accessible only to authorized personnel who have clearly established their identity.

(l) The hospital shall develop and implement a policy for the facility to be smoke-free by April 1, 1995. The hospital shall ensure that there is no smoking in the facility by employees, visitors or patients.

(m) The hospital shall develop and implement a method to prevent smoking by patients who have been designated as "not responsible".

8:43G-5.3 Administrative and hospital-wide staff qualifications

(a) The administrator or chief executive officer of the hospital shall have at least one of the following qualifications:

1. A master's degree and at least three years of full-time experience in progressively responsible management positions;

2. A baccalaureate degree and at least five years of full-time experience in progressively responsible management positions; or

3. At least 10 years of full-time experience in hospital administration.

(b) The hospital shall verify through visual examination the professional credentials, required by this chapter, of all new employees.

(c) The hospital shall verify through visual examination that the professional credentials, required by this chapter, of all employees are current.

(d) If the hospital performs organ transplants, the director of the medical staff shall ensure that all health professionals serving the patient have sufficient clinical experience in transplantation care, based on predetermined criteria established in hospital policies and procedures or set by the National Organ Procurement and Transplantation Network.

8:43G-5.4 Organ and tissue donation

(a) The hospital shall develop and implement written protocols for organ and tissue donation in accordance with N.J.S.A. 26:6-57 et seq., and the Uniform Anatomical Gift Act, P.L. 1969, c.161, as amended.

(b) For the purposes of this rule, the following words shall have the following meanings:

1. "Designated requestor" means a hospital employee who has completed a course offered or approved by the designated Federally qualified organ procurement organization. This course shall be designed by the OPO with input from the regional tissue and eye bank community and shall incorporate the methodology to be used by the Designated Requestor for approaching potential donor families to request organ or tissue donation.

2. "OPO" means a hospital's designated Federally qualified organ procurement organization. The Federally qualified organ procurement organizations in New Jersey are:

i. The New Jersey Organ and Tissue Sharing Network

150 Morris Avenue
Springfield, New Jersey 07081
(800-541-0075); and

ii. Delaware Valley Transplant Program
2000 Hamilton Street
Philadelphia, Pennsylvania 19130
(800-543-6391)

3. "Organ" means human kidney, liver, hear, lung, pancreas, and any other solid organ.

4. "Tissue" means human skin, heart valves, saphenous veins, bone and other tissue, including ocular tissue.

5. "Transplant recovery specialist" means a medical professional licensed by the State of New Jersey or another State or technician trained by an organ procurement organization in accordance with Federal standards pursuant to 42 U.S.C. § 274(b) and nationally accredited standards for human body part removal.

(c) The protocols required by (a) above shall include, at a minimum, the following:

1. Procedures for the hospital to notify its OPO of each hospital patient whose death is imminent or who died in the hospital at or around the time of death of such hospital patient. The information to be provided by the hospital to its OPO shall include the following:

i. Patient's name and identifier number;

ii. Patient's age;

iii. Cause of death or anticipated cause of death;

iv. Past medical history; and

v. Other pertinent medical information requested by the OPO;

2. A requirement that hospital personnel note in the patient's medical record the donor suitability determination made by the OPO. If the patient is determined to be an unsuitable candidate for donation, an explanatory notation shall be made part of the patient's medical record;

3. A requirement that, if the patient has a validly executed donor card, will, or other document of gift, driver's license or identification care evidencing anatomical gift, the OPO representative or the Designated Requestor, if any, shall attempt to notify an appropriate person under N.J.S.A. 26:6-58.1 to advise him or her of the gift. If there is no document of gift available to the OPO representative or Designated Requestor, he or she shall ask persons pursuant to N.J.S.A. 26:6-58.1 whether the decedent had a validly executed document of gift. If there is no such evidence of an anatomical gift, then the person designated under N.J.S.A. 26:6-58.1 shall be informed of the option to donate organs and tissue. A person authorized or under obligation to dispose of the body pursuant to N.J.S.A. 26:6-58.1(b)(6) shall include, but not be limited to, a hospital administrator, a designated health care representative, a holder of a durable medical power of attorney, or a person named in the decedent's will.

4. A requirement that a notation shall be made in a deceased person's medical record indicating whether or not consent for organ or tissue donation was granted. The notation shall include the following information:

i. Whether consent was granted or refused;

ii. The name of the person granting or refusing consent;

iii. That person's relationship to the decedent; and

iv. Documentation of telephone contact with the OPO.

5. A provision that the hospital shall permit the OPO to review the medical records of all deceased patients, as long as the OPO has agreed, in writing, to maintain the confidentiality of any patient identifying information.

6. A requirement that discretion and sensitivity to family circumstances and beliefs shall be maintained in all discussions regarding donations of organs, tissue or eyes.

(d) The hospital shall identify the position or job title of the person at the hospital who shall be responsible for serving as a hospital liaison to the hospital's OPO, and as coordinator of the hospital's donor activities. The hospital, in conjunction with the OPO shall provide in service training to such individuals. Such individual shall be responsible for overseeing the development and implementation of the hospital's protocols established in accordance with subsection (c) above.

(e) Recovery of human body parts for donation may be performed by a transplant recovery specialist. A physician is not required to be present during the recovery procedure.

(f) If the hospital performs organ transplants, the director of the medical staff shall ensure that satisfactory follow-up care and consultation are provided to all transplantation patients, including multidisciplinary conferences held at periodic intervals.

(g) If the hospital provides bone or tissue banking services, the hospital shall meet all guidelines set by the American Association of Tissue Banks for such services. Such guidelines are incorporated herein by reference and are available from the American Association of Tissue Banks, 1350 Beverly Road, Suite 220A, McLean, VA 22101 (703-827-9582).

8:43G-5.5 Administrative and hospital-wide patient services

(a) To meet the needs of pediatric patients, the hospital shall have available medical and nursing staff with specialized pediatric training and shall have equipment adaptable to the needs of pediatric patients on-site.

(b) The hospital shall ensure the safe transport of patients within the hospital, according to each patient's medical needs. This system shall include at least interdepartmental reporting of incidents and changes in the patient's condition during transportation and during the period the patient is in another service and providing an accompanying health professional for those patients whose condition warrants it.

(c) The hospital shall provide interpretive 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.

(d) The hospital shall have a system to link patients with clergy or spiritual counselors, upon request.

(e) For patient and staff safety, the hospital shall have a security system which is rigidly enforced and includes at least an identification system for employees, volunteers, and medical staff and control of access to and egress from the hospital.

(f) There shall be a means to summon immediate emergency response for medical emergencies occurring in the hospital.

(g) Each department in the hospital providing direct patient care shall have a health care professional capable of initiating cardiopulmonary resuscitation on duty at all times when patients are present.

8:43G-5.6 Reportable events

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

1. An unscheduled interruption for three or more hours of physical plant and/or clinical services essential to the health and safety of patients and employees;

2. All fires, disasters or accidents which result in serious injury or death of patients or employees, or in evacuation of patients out of the facility;

3. All alleged or suspected crimes which endanger the life or safety of patients or employees, which are also reportable to the police department, and which result in an immediate on-site investigation by the police.

(b) Information received by the Department of Health through immediate notification shall not be disclosed to the public in such a way as to indicate the names of the specific patients or hospital employees to whom the information pertains.

(c) A follow-up written report shall be submitted to the Department within seven calendar days of the event, unless determined not to be necessary by the Department. The written report shall contain information about injuries to patients and/or staff, disruption of services, extent of damages and corrective actions taken.

8:43G-5.7 Administrative and hospital-wide staff education

(a) There shall be a formal orientation program for all new permanent staff that includes at least training in patient rights as found at N.J.A.C. 8:43G-4, a tour of the hospital, orientation to the hospital's security system and disaster plan, and review of procedures to follow in case of an emergency.

(b) There shall be a formal orientation program for all new temporary staff, nurses retained through an outside agency, and persons providing services by contract which includes, at a minimum, a tour of the department to which the individual is assigned, orientation of the hospital's security system, and review of procedures to follow in case of an emergency.

(c) The hospital shall provide, evaluate, and coordinate training and educational programs for all departments in the hospital.

8:43G-5.8 (Reserved)

8:43G-5.9 Department education programs

(a) Each department in the hospital shall develop, revise as necessary, and implement a written plan of staff education. The plan shall address the education needs, relevant to the service, of different categories of staff on all work shifts. The plan shall include education programs conducted at least annually in the service, in other areas of the hospital, or off-site.

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

1. Orientation of new staff to the 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. Supervisor judgements about education needs based on assessment of staff performance;

5. Education on statutory requirements relevant to the specific service such as identification and reporting of victims of abuse; and

6. Areas identified by the hospital-wide quality assurance program as needing educational programs; and

7. Patient rights; and

8. Rights and responsibilities of staff under the New Jersey Advance Directives for Health Care Act (P.L. 1991, c.201) and the Federal Patient Self Determination Act (P.L. 101-508), and internal hospital policies and procedures to implement these laws.

(c) Implementation of the plan shall include records of attendance for each program and composite records of participation for each staff member.

8:43G-5.10 Funding for regionalized services

(a) All hospitals providing emergency room services shall be members in good standing of the New Jersey Poison Information and Education System established pursuant to N.J.S.A. 26:2-119 et seq.

(b) All hospitals with licensed obstetric or pediatric beds or designated as a Community or Regional Perinatal Center pursuant to N.J.A.C. 8:33C shall be a member in good standing of a Maternal and Child Health Consortium as defined in N.J.A.C. 8:35.

(c) Prior to the designation of the Maternal and Child Health Consortium pursuant to the certificate of need process and after the expiration of the Robert Wood Johnson Foundation funding for consortia on or before March 1, 1993, all hospitals eligible for a perinatal adjustment in a 1993 revenue cap approved by the Hospital Rate Setting Commission shall make monthly payments based on that adjustment to the Maternal and Child Health Consortium to which they belong.

8:43G-5.11 Occupational health structural organization

(a) There shall be an employee-management occupational health and safety committee that:

1. Meets a minimum of six times a year;

2. Establishes a procedure for receiving and responding to employees' occupational health and safety complaints and concerns;

3. Receives, investigates, and provides written or oral responses to employees' complaints related to occupational health and safety;

4. Provides information to the hospital staff including recommendations or actions taken by the committee;

5. Assists in the development and periodic review of all occupational health and safety policies; and

6. Conducts inspections to assure conformance with those policies and procedures, and to identify problems.

8:43G-5.12 Occupational health policies and procedures

(a) The hospital shall develop and implement a written policy to assure that staff have the right to voice occupational health and safety complaints or problems without reprisals.

(b) The hospital shall have available the most current version of standards and guidelines for:

1. Cytotoxic (antineoplastic) drugs: "Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," Occupational Safety and Health Administration (OSHA) Instruction PUB 8-1.1, Office of Occupational Medicine, OSHA;

2. Waste anesthetic gases: "Recommended Standard for Occupational Exposure to Waste Anesthetic Gases and Vapors," National Institute of Occupational Safety and Health (NIOSH) Publication No. 77-140;

3. Federal regulations for ethylene oxide, Code of Federal Regulations: 29 CFR 1910.1047;

4. Federal regulations for formaldehyde, Code of Federal Regulations: 29 CFR 1910.1048;

5. Federal regulations for hazard communication, Code of Federal Regulation: 29 CFR 1910.1200 (required for private sector hospitals); and

6. New Jersey Workers and Community Right to Know Act, N.J.S.A. 34:5A-1 et seq., and all rules promulgated pursuant to that Act.

Note: Copies of these standards and guidelines can be obtained from:

Occupational Health Services
PO Box 360
Trenton, NJ 08625-0360

(c) The hospital shall have available and shall comply with the most current version of the following guidelines, incorporated herein by reference, to protect health care workers who may be exposed to infectious blood-borne diseases, such as AIDS and hepatitis-B:

1. "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)", OSHA Instruction CPL-2-2.44B, August 15; February, 1990;

2. "Recommendations for Prevention of HIV Transmission in Health-Care Settings," CDC, Morbidity and Mortality Weekly Report (MMWR) 1987; Volume 36 (supplement 2S); and

3. "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings," CDC Morbidity and Mortality Weekly Report (MMWR) 1988; Volume 37.

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

(d) The hospital shall use the CDC, NIOSH, and OSHA standards and guidelines specified in (b) and (c) above to develop written occupational health policies and procedures that are reviewed annually, revised as needed, and implemented. They shall include at least:

1. Protection of employees from cytotoxic drugs, waste anesthetic gases, ethylene oxide, and formaldehyde; and

2. Protection and management of needle-stick injury and blood or body fluid exposures for all employees.

8:43G-5.13 Occupational health staff qualifications

The hospital shall designate an individual to provide clinical guidance on occupational health and safety issues who is a physician with occupational medicine background, an industrial hygienist, or a health professional with two years of experience in occupational health.

8:43G-5.14 Occupational health education

(a) The hospital shall develop, revise as necessary, and implement a written plan of staff education. The plan shall address the education needs of different categories of employees with potential exposure to hazardous substances, including at least cytotoxic drugs, waste anesthetic gases, ethylene oxide, formaldehyde, and/or hazardous blood-borne diseases on all work shifts. The plan shall include education programs conducted in the employees' service, in other areas of the hospital, and off-site.

(b) The plan shall include on-going education programs and an orientation session that address at least the following:

1. Written materials that the employee can use for reference;

2. Information about the risks associated with these hazardous materials and/or blood-borne diseases;

3. Information about employees' responsibilities to use personal protection clothing or equipment;

4. Education and training programs for employees that comply with rules and regulations concerning the establishment and contents of such programs as required by the Hazard Communications Standard (OSHA 29 CFR 1910.1200) or the New Jersey Worker and Community Right to Know Act (N.J.S.A. 34:5A-1 et seq.).

Note: Copies of "New Jersey Worker and Community Right to Know Act Educational and Training Program Guide" are available from:

Occupational Health Service
PO Box 368
Trenton, New Jersey 08625-0368

(c) An orientation session shall occur before the employee is exposed to or begins working with hazardous materials or patients with hazardous blood-borne diseases.

(d) Implementation of the education plan shall include records of attendance for each program and composite records of participation for each staff member.

8:43G-5.15 Occupational health continuous quality improvement methods

There shall be a program of continuous quality improvement for occupational health that is integrated into the hospital continuous quality improvement program and includes regularly collecting and analyzing data to help identify occupational health problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

8:43G-5.16 Disaster planning

(a) The hospital shall have a written, comprehensive disaster plan. The disaster plan, and any updates or changes to it, shall be submitted to the Inspection Service Program within the New Jersey State Department of Health and shall include the following:

1. Identification of potential hazards that could necessitate an evacuation, including internal and external disasters such as a natural disaster, labor work stoppage, or industrial or nuclear accidents;

2. Emergency procedures for evacuation of the hospital;

3. Comprehensive measures for receiving and managing care for a large influx of emergency patients. These measures shall include the roles of, at least, the emergency department, surgical suite, and patient care units;

4. Comprehensive plans for receiving patients who are being relocated from another facility due to a disaster. This plan shall include at least an estimate of the number and type of patients the facility would accommodate;

5. Procedures in the case of interruption of utilities services in a way that affects the health and safety of patients;

6. Identification of the facility and an alternate facility to which evacuated patients would be relocated;

7. The estimated number of patients and staff who would require relocation in the event of an evacuation;

8. The system or procedure to ensure that medical charts accompany patients in the event of patient evacuation, and that supplies, equipment, records, and medications would be transported as part of an evacuation; and

9. The roles and responsibilities of staff members in implementing the disaster plan.

(b) The hospital shall assure that patients receive nursing care throughout the period of evacuation and while being returned to the original hospital.

(c) The hospital shall ensure that evacuated patients who are not discharged are returned to the hospital after the emergency is over, unless the patient prefers to remain at the receiving facility or be discharged instead of being returned to the original hospital.

(d) Any staff member who is designated as the acting administrator shall be knowledgeable about, and authorized to implement, the hospital's plans in the event of an emergency.

(e) The hospital administrator shall appoint a disaster planner for the hospital. The disaster planner shall meet with county and municipal emergency management officials at least annually to review and update the written, comprehensive disaster plan. If county or municipal officials are unavailable for this purpose, the hospital shall notify the New Jersey State Office of Emergency Management, Division of State Police, Department of Law and Public Safety, P.O. Box 7068, River Road, West Trenton, NJ 08628 (phone: 609-882-2000).

(f) While developing the hospital's plan for evacuating patients, the disaster planner shall communicate with the facility or facilities designated to receive relocated patients.

(g) Copies of the current plans for receiving and evacuating patients in the event of a disaster shall be sent to municipal and county emergency management officials and to the designated receiving facilities.

(h) The hospital shall conduct at least one evacuation drill each year, either simulated or using selected patients. An actual evacuation shall be considered a drill, if it is documented.

(i) The hospital shall conduct at least one drill each year in which a large influx of emergency patients is simulated. An actual emergency of this type shall be considered a drill, if it is documented.

(j) The hospital shall maintain at least a three-day supply of food and have access to an alternative supply of water in case of an emergency.

(k) The hospital shall take corrective action if the temperature of the hospital is not in compliance with the requirements specified in Chapter 7 of the Guidelines for Construction and Equipment for Hospital and Medical Facilities (published by the American Institutes of Architects Press, 1735 New York Ave NW, Washington, D.C. 20006, publication # ISBNO-913962-96-1) for a continuous period of four hours or longer. The hospital shall notify the New Jersey State Department of Health if the corrective action is not effective.

8:43G-5.17 (Reserved)

8:43G-5.18 Blood bank

(a) The governing board shall designate the pathologist or other qualified physician as physician-in-charge of the blood service.

(b) The hospital shall maintain an emergency supply of blood and shall have access to additional supplies as needed.

(c) The hospital shall maintain a current list of potential blood donors of all principal blood types and groups who are available in emergencies or it shall establish a stable source of blood supply, either through an integrated blood operation or by arrangement with an outside blood service.

8:43G-5.19 Clinical and pathological laboratories

(a) The laboratories shall be under the direction of a pathologist on a full or part time basis.

(b) A qualified member of the medical staff may be appointed by the governing authority to assume a portion of the responsibilities involved, with a pathologist as a consultant.

8:43G-5.20 Electrocardiogram laboratory

The hospital shall provide at least one room designated for electrocardiography. Sufficient space shall be provided for the maintenance of essential records and such office space as may be required.

8:43G-5.21 Out-patient and preventive services

(a) All hospitals shall provide, on a regular and continuing basis, out-patient and preventive services, including clinic services for medically indigent patients, in those services provided on an in-patient basis.

(b) In no instance shall a hospital provide less than out-patient services in medicine and surgery.

SUBCHAPTER 6. ANESTHESIA

8:43G-6.1 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 major 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 agent 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 tranqualization 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 opthalmologic surgical procedures, such as treatment of chalazions and non-invasive 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, dentist or podiatrist.

"Privileges" means having been granted permission by a hospital to provide specified anesthesia services, such as 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 hospital location in which special procedures are performed.

"Supervision" means responsibility by a physician who has obtained privileges in accordance with medical staff bylaws, and is immediately available on- site overseeing the administration and monitoring of anesthesia by anesthesia personnel. Immediately available on-site means that the supervising physician is present and available to respond and proceed immediately to the anesthetizing location.

"Universal precautions" means a set of precautions, in accordance with the Centers for Disease Control and Prevention published guideline for Handwashing and Hospital Environmental Control. That publication may be obtained by telephoning the Centers for Disease Control and Prevention at (800) 311-3435.

8:43G-6.2 Anesthesia services, policies and procedures

(a) Anesthesia services shall be administered in accordance with written policies and procedures that are reviewed at least every three years, and revised more frequently as needed. They shall include at least the following:

1. Monitoring of patients in the postanesthesia care unit, including availability of monitoring equipment, and discharge from the postanesthesia care unit;

2. Monitoring of patients in any special procedure rooms where patients receive anesthesia;

3. Reporting of morbidity and mortality; and any unusual or untoward occurrences in compliance with N.J.A.C. 8:43G-6.10 (c); and

4. Preanesthesia evaluation, patient preparation and intraoperative management.

8:43G-6.3 Anesthesia staff: qualifications for administering anesthesia

(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.

(b) The physician director of anesthesia services shall participate in the credentialing process and delineation of privileges of all personnel who administer anesthetic agents. Criteria for hospital-wide anesthesia credentialing shall include at least:

1. Objective measures of training and experience in anesthesia care against which all candidates are evaluated; and

2. A requirement for continuing education in anesthesia care.

(c) All anesthesia providers, except for those in accordance with N.J.A.C. 8:43G-12.3(c) 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 hospital only in accordance with medical staff policies and procedures.

(e) 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 hospital's policy.

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

(g) 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.

(h) 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 and who is immediately available:

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; 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 remains present.

(i) The monitoring of patients who have been given 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, and 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 (h) above;

2. A registered professional nurse or

3. For bronchoscopic procedures only, a licensed respiratory care therapist.

(j) 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;

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; 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; 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.

(k) Minor regional blocks shall be monitored in accordance with the hospital's policy.

(l) Provision shall be made for remote monitoring of the patient if radiation or another direct hazard necessitates the removal of personnel.

8:43G-6.4 Anesthesiologist availability

At all times, an anesthesiologist shall be on-site or on-call and available to reach the hospital within 30 minutes under normal transportation conditions.

8:43G-6.5 Anesthesia patient services

(a) A preanesthesia note, reflecting evaluation of the patient and review of the patient record prior to administration of anesthesia, shall be made or certified 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.

(b) 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.

(c) Upon arrival in the postanesthesia care unit a postanesthesia note shall be entered into the patient’s anesthesia record by a member of the hospital’s anesthesia team.

(d) An anesthesia team member shall make a postoperative discharge note for inpatients prior to the patient leaving the postanesthesia care unit and at the time of discharge for outpatients.

8:43G-6.6 Anesthesia supplies and equipment; safety systems

(a) Diameter index safety systems or equivalent 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 supply 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 or carbon dioxide monitors, improperly positioned breathing-circuit sensors, or other insufficiencies.

8:43G-6.7 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; name of servicing agent; work performed; and date of 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 be determined by the hospital's physician director 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 hospital's anesthesia services and approved by the hospital's 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 a single phrase explanation.

8:43G-6.8 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, and 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) The capacity for invasive monitoring of arterial pressure shall exist within the operating suite.

(i) A difficult airway container or cart shall be immediately available in each anesthesia department for handling emergencies. The following items are required for inclusion in the difficult airway container or cart: resuscitation equipment, emergency drugs, a laryngeal mask airway, or other items of similar technical capability.

(j) 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.

(k) A peripheral nerve stimulator shall be available in 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.

(l) 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 monitored subsequently in accordance with hospital protocol.

(m) 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 post anesthesia care unit.

8:43G-6.9 Anesthesia staff education and training

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

8:43G-6.10 Anesthesia continuous quality improvement

(a) The hospital'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 hospital 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) The continuous quality improvement program shall include morbidity and mortality conferences.

(c) The hospital 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 events or outcomes related to anesthesia, except those in which the patient expired prior to the administration of anesthesia, or in which the patient was categorized as ASA Class IV or ASA Class V according to the American Society of Anesthesiology (ASA) classification system.

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.

SUBCHAPTER 7. CARDIAC

8:43G-7.1 Scope and definitions

(a) The standards set forth in this subchapter shall apply only to separate, designated units or services for adult and/or pediatric cardiac surgery, cardiac catheterization, and interventional cardiac procedures. All hospitals licensed to provide any of these services shall also comply with all applicable staffing, staff qualification, volume, equipment and physical plant requirements contained in N.J.A.C. 8:33E.

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

"Cardiac catheterization" means the insertion of a thin, flexible tube (catheter) into a vein or artery and guiding it into the heart for purposes of determining cardiac anatomy and function.

"Cardiac surgery center" means a facility capable of providing invasive diagnostic catheterization, and all treatment modalities including open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG) surgery, PTCA and EPS studies.

"Complex electrophysiology study" (EPS) means the more complex variety of electrophysiology study, in contrast to non-complex electrophysiologic procedures, which primarily involve His Purkinje conduction evaluation without arrhythmia induction. EPS includes:

1. Procedures which intend to induce ventricular or supraventricular tachycardia;

2. Activation sequence mapping of cardiac tachyarrhythmias;

3. Electrode catheter ablative procedures; and

4. Implantation of anti-tachyarrhythmia devices and implantable cardioverter defibrillators.

"Diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without surgery backup. These facilities have laboratories which perform procedures on at least 500 patients annually.

"Hospital-based" means the provisions of a health care service that is physically located on the campus of, and is a permanent structure within, a licensed care hospital offering inpatient support services.

"Left-heart catheterization" means the measurement of left heart hemodynamics and definitions of left heart anatomy/function by catheter delivered radiopaque contrast media.

"Low-risk patients" means those patients excluded from the definition of "high risk" who are able to be managed by the pilot facilities for diagnostic cardiac catheterization, as defined at N.J.S.A. 26:6-57 et seq.

"Open heart surgery" refers to a procedure using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric cardiac surgery centers" means cardiac surgery centers specifically designated to provide the full range of invasive cardiac diagnostic therapeutic and surgical services to patients less than 16 years of age.

"Pilot catheterization program" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services within its permanent structure as defined in "hospital-based" above that is limited in the provision of its service to low risk adult patients. Patients with the following conditions listed below are to be considered high risk and shall be excluded from catheterization at pilot facilities and transferred in accordance with N.J.A.C. 8:33E-1.8:

1. Left main coronary syndrome;
2. Unstable myocardial infarction;
3. Acute myocardiac infarction within three days;
4. Unstable angina with persistent angina;
5. Congestive heart failure, defined as NYHA Class II or IV;
6. Cardiogenic shock or severe hemodynamic instability;
7. Aortic stenosis, as measured by Doppler mean gradient over 40 mm of Hg;
8. Ejection fraction below 30 percent; or
9. Concomitant severe medical or vascular problems.

"Percutaneous transluminal coronary angioplasty" (PTCA) means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PTCA also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

8:43G-7.2 Cardiac surgery policies and procedures

(a) At least 350 open-heart operations shall be performed at each licensed cardiac surgical center by the end of the third year of operation and annually thereafter as referenced at N.J.A.C. 8:33E-2.3(a)1 and 2.

(b) The hospital shall have in effect policies and procedures which ensure that priority laboratory services will be available to cardiovascular patients if medically indicated.

8:43G-7.3 Cardiac surgery staff qualifications

(a) There shall be a director of the cardiac surgery service who is board certified in thoracic surgery.

(b) The primary surgeon shall be board certified in thoracic surgery, or shall meet current requirements to be examined and shall be examined within two years of eligibility.

(c) The surgeon in charge of a cardiac operation shall be assisted by a physician board certified in thoracic surgery, a thoracic surgery resident or a physician with privileges to assist in the specific procedure and with prior approval from the physician director of the cardiac surgery service.

(d) The cardiovascular surgical intensive care service or recovery room shall have a physician director, who may be the director of cardiac surgery.

(e) The cardiac perfusionist for each cardiac surgical procedure shall have graduated from an educational program for perfusionists accredited by the Council on Allied Health Education Administration (CAHEA) and be certified by the American Board of Cardiovascular Perfusion or shall meet current requirements to be examined and shall be examined within two years of eligibility; or during each of the past two years shall have performed at least 75 cardiac perfusions.

8:43G-7.4 (Reserved)

8:43G-7.5 Cardiac surgery staff time and availability

(a) There shall be at least a ratio of one registered professional nurse to one patient during the patient's stay in the cardiovascular surgical intensive care service or recovery room until the patient is stabilized.

(b) For patients who remain in the cardiovascular surgical intensive care service or recovery room beyond the initial period of stabilization, there shall be at least a ratio of two registered professional nurses to three such patients.

(c) Following reclassification or transfer of the patient to an intermediate level of care, nurse staffing shall be in accordance with N.J.A.C. 8:43G-9.20(a)6.

(d) An anesthesiologist responsible for providing anesthesia care during cardiac surgery shall meet one of the following qualifications:

1. Is board certified in anesthesiology, and has completed additional training in providing anesthesia care during cardiac surgery; or

2. Is board eligible in anesthesiology, has completed additional training in providing anesthesia care during cardiac surgery, and is examined for certification within two years of initial anesthesia board eligibility.

(e) An anesthesiologist or certified registered nurse anesthetist experienced in cardiac surgery and with hospital privileges for providing anesthesia care during cardiac surgery shall be available in the surgical suite to assist the anesthesiologist for each cardiac surgical procedure.

(f) There shall be a physician in the hospital at all times who is able to manage cardiac emergencies in the surgical intensive care service or recovery room.

(g) During the entire period of the patient's stay in the cardiovascular surgical intensive care service or recovery room, the operating surgeon or a designated alternate shall arrive at the hospital within 30 minutes of being summoned for an emergency.

(h) A physician who is board certified in internal medicine, in the subspecialty of cardiovascular disease, or other designated physician shall be in the hospital and available for assistance whenever cardiac surgery is being performed.

(i) One registered professional nurse who is certified in basic cardiac life support and trained and experienced in assisting cardiac surgery shall be in each operating room when cardiac surgery is performed. There shall be an additional assistant in each operating room who is a registered professional nurse, licensed practical nurse, or technician.

(j) A perfusionist who is certified by the American Board of Cardiovascular Perfusion or meets the experience requirements shall be available to operate the perfusion pump for each cardiac surgical procedure. A second perfusionist meeting the same requirements shall be available in the surgical suite to assist. In emergency cases, a second perfusionist may be off-site and readily summoned if needed.

8:43G-7.6 (Reserved)

8:43G-7.7 Cardiac surgery patient services

(a) Reports of diagnostic and operative procedures performed by cardiac services shall be dictated for inclusion in the medical record not later than 48 hours after completion of the procedure.

(b) A note by the physician performing the procedure shall be included in the patient's medical record immediately after completion of the cardiac procedure.

(c) Counseling by trained and experienced professionals shall be available to assist pre/post operative cardiac patients/families to cope with the crisis of illness, adjustment to hospitalization, plans for patient's care post-discharge, or bereavement and loss.

8:43G-7.8 Cardiac surgery space and environment

There shall be a cardiac surgical intensive care service or recovery room dedicated specifically to patients from the cardiac surgical service.

8:43G-7.9 Cardiac surgery supplies and equipment

(a) The cardiac surgical intensive care service or recovery room shall have equipment and staff for the following:

1. Hemodynamic and electrocardiogram monitoring;

2. Pacemaker usage;

3. Cardiopulmonary resuscitation;

4. Arrhythmia detection and treatment; and

5. Intra-aortic balloon-assisted circulation.

8:43G-7.10 Staff education

Requirements for the cardiac service staff education program shall be as provided at N.J.A.C. 8:43G-5.9.

8:43G-7.11 (Reserved)

8:43G-7.12 Cardiac surgery continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for all cardiac services that is integrated into the hospital quality continuous improvement program and 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.

(b) The continuous quality improvement program for cardiac surgery, percutaneous transluminal coronary angioplasty (PTCA), and electrophysiology studies (EPS) shall include at least:

1. Monitoring the volume of each service provided;

2. Infection and complication rates;

3. The incidence of mortality, morbidity, and other adverse occurrences in each service;

4. Patient factors that affect risk of complications in each service; and

5. Retrospective evaluation of emergency procedures in each service.

8:43G-7.13 (Reserved)

8:43G-7.14 Cardiac catheterization policies and procedures

(a) Cardiac catheterization services shall be promptly accessible in a hospital setting, either on-site or by immediate transfer, in which case there shall be a written transfer agreement.

(b) The cardiac catheterization laboratory shall perform a minimum of 500 catheterizations, per year excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-1.4(b)1.

(c) The cardiac catheterization laboratory shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and followed. They shall include at least policies and procedures that assure aseptic practices and radiologic safety.

(d) For all procedures in the cardiac catheterization laboratory a postcatheterization report shall be entered in the patient's medical record immediately after the procedure. This report shall include at least:

1. A description of the procedure, by the physician;

2. Preliminary presentation of the results, by the physician;

3. The patient's condition upon discharge from the laboratory by the physician;

4. Postcatheterization orders, by the physician;

5. Complications, if applicable, by the physician;

6. Medications and anesthesia given;

7. The patient's condition upon discharge; and

8. Palpation of pulses.

8:43G-7.15 Cardiac catheterization staff qualifications

(a) There shall be a director of cardiac catheterization who is board certified in internal medicine in the subspecialty of cardio-vascular disease, and who has completed at least one year of additional training in cardiac catheterization and has performed at least 200 cardiac procedures as the primary operator.

(b) Any physician performing cardiac catheterization as primary operator in the cardiac catheterization laboratory shall meet one of the following qualifications:

1. Is board certified in internal medicine and the subspecialty of cardiovascular disease and has completed the current training and experience requirement in cardiac catheterization, including twelve months experience in the cardiac catheterization laboratory, as required by the American Board of Internal Medicine; or

2. Is board eligible in the subspecialty of cardiovascular disease, has completed the current training and experience requirement in cardiac catheterization, including 12 months experience in the cardiac catheterization laboratory, as required by the American Board of Internal Medicine, and is examined for certification within two years of initial cardiac board eligibility.

(c) Each physician performing diagnostic cardiac catheterization and angiography without supervision shall have performed at least 200 cardiac catheterizations or angiography studies as the primary operator.

(d) Each physician shall perform a minimum of 50 procedures per year with a minimum of 100 procedures over a two year period.

(e) The circulating nurse in the cardiac catheterization laboratory shall be certified in basic cardiac life support.

8:43G-7.16 Cardiac catheterization staff time and availability

(a) The following staff shall be present for all cardiac catheterization procedures:

1. A physician who meets the requirements in N.J.A.C. 8:43G-7.15(b);

2. A registered professional nurse, trained and experienced in assisting in cardiac catheterization procedures, who acts as the circulating nurse; and

3. One of the following:

i. A scrub nurse, who is either a registered professional nurse or a licensed practical nurse; or

ii. A technician, who has been trained in assisting in cardiac catheterization procedures.

8:43G-7.17 Cardiac catheterization patient services

Handwashing between contacts with patients shall be performed using an antimicrobial agent by all personnel involved in patient care in the cardiac catheterization laboratory.

8:43G-7.18 Cardiac catheterization space and environment

(a) All persons entering the cardiac catheterization laboratory shall be attired in scrub suits. Limited access people may wear cover gowns or jumpsuits as substitutes.

(b) The procedure room in the cardiac catheterization laboratory shall have a minimum clear area of 400 square feet exclusive of fixed and movable cabinets and shelves, with a minimum dimension of 20 feet.

(c) There shall be a control room in the cardiac catheterization laboratory that is at least 50 square feet and is large enough to contain and provide for the efficient functioning of the x-ray equipment and image recording equipment.

(d) The cardiac catheterization laboratory shall have an equipment room or enclosure large enough to contain the x-ray transformers, power modules, associated electronics, and electrical gear. This room or enclosure shall be at least 100 square feet and shall be positioned in the laboratory to ensure short high-voltage cables. There shall be ready access to the equipment for servicing.

(e) There shall be a patient holding area or recovery room where patients are under visual observation before and after the procedure.

(f) Scrub facilities shall be located adjacent to the entrance to the procedure room, and shall be arranged to minimize incidental splatter on nearby personnel, medical equipment, or supply carts.

(g) There shall be an enclosed soiled workroom within the cardiac catheterization suite. The workroom shall contain at least:

1. A clinical sink or equivalent flushing-type fixture;

2. A sink equipped for handwashing;

3. A work counter;

4. A waste receptacle; and

5. A linen receptacle.

(h) There shall be a clean holding room or workroom for the storage of clean and sterile supplies. This room shall have a sink equipped for handwashing.

(i) There shall be a system in the cardiac catheterization laboratory that ensures the removal and processing of soiled instruments and the immediate availability of sterile supplies.

(j) The change area for the cardiac catheterization laboratory staff shall be arranged to ensure a one-way traffic pattern so that personnel entering from outside the cardiac catheterization suite can enter, change their clothing, and move directly into the catheterization laboratory.

(k) There shall be a housekeeping closet containing a floor receptor or service sink and storage for housekeeping supplies provided for the exclusive use of the cardiac catheterization suite.

(l) During scheduled hours of operation, personnel who have received special training in cleaning the cardiac catheterization suite shall be assigned to the suite for cleaning and related duties.

(m) Space with x-ray and cine equipment shall be available to the cardiac catheterization suite for the development of films.

(n) The following shall be readily available for use by the cardiac catheterization suite:

1. A viewing room;

2. A film file room;

3. A conference room;

4. A library and study room; and

5. Teaching aids and files.

(o) There shall be an emergency call system in the cardiac catheterization procedure and recovery room.

8:43G-7.19 Cardiac catheterization supplies and equipment

(a) All cardiac catheterization laboratory linens and apparel shall be laundered in the laundry services provided by the hospital.

(b) The cardiac catheterization laboratory shall be equipped with radiological equipment strong enough to produce an image and in accordance with N.J.S.A. 26:2D-1 et seq.

(c) Fluoroscopic radiological equipment shall be installed in such a way that either it can be easily moved around the patient or the patient table can be adjusted mechanically in order to get the desired views.

8:43G-7.20 Cardiac catheterization staff education and training

Requirements for the cardiac catheterization staff education program shall be as provided at N.J.A.C. 8:43G-5.9.

8:43G-7.21 Cardiac catheterization quality assurance methods

(a) The quality assurance program for cardiac catheterization shall include at least:

1. Monitoring the volume of procedures;

2. Infection and complication rates;

3. The incidence of mortality, morbidity, and other adverse occurrences;

4. Patient factors that affect risk of complications in each service; and

5. Retrospective evaluation of emergency procedures.

(b) There shall be a peer review committee for the cardiac catheterization service that includes at least the chief of the cardiac catheterization laboratory, the chief of cardiology, a catheterizing cardiologist, and a non-catheterizing cardiologist. The committee shall review all mortalities, serious complications, and selected procedures done in the cardiac catheterization suite to identify trends and problems in the service. Minutes of these meetings shall be maintained.

8:43G-7.22 Scope of pilot catheterization program

In addition to meeting all applicable standards in N.J.A.C. 8:43G-7.1 through 7.21, a pilot catheterization program established in accordance with N.J.A.C. 8:33E shall comply with all standards in N.J.A.C. 8:43G- 7.23 through 7.27.

8:43G-7.23 Requirements for licensure

(a) Initial licenses granted to pilot catheterization program facilities shall be valid for a period not to exceed 30 months from the month in which the facility initiates low risk invasive cardiac diagnostic services under the program and shall expire automatically without the need for further notification or other action by the Department of Health and Senior Services.

(b) Licenses that have expired at accordance with (a) above shall be renewed only upon demonstration of full compliance with all applicable standards and criteria for low risk invasive cardiac diagnostic pilot catheterization programs.

8:43G-7.24 Pilot catheterization program policies and procedures

The pilot catheterization program shall perform a minimum of 350 left-heart catheterizations annually by the end of the second year of operation. In accordance with N.J.A.C. 8:33E-1.14, the program shall demonstrate and verify its ability to provide at least this level of service in order to obtain renewal of its license.

8:43G-7.25 Pilot catheterization program staff qualifications

(a) There shall be a physician director of the program who is board certified in internal medicine in the subspecialty of cardiovascular disease. The director shall have completed at least one year of additional training and performed at least 200 cardiac procedures as the primary operator.

(b) The director shall perform at least 150 left-heart catheterization procedures per year, at least 100 of which shall be performed at the pilot program laboratory.

(c) Any physician performing invasive cardiac procedures in the pilot catheterization program shall meet the qualifications at N.J.A.C. 8:43G-7.15(b) and (c).

(d) Each physician with privileges in the pilot program laboratory shall perform at least 50 left-heart catheterization per year.

8:43G-7.26 Pilot catheterization program staff time and availability

(a) There shall be at least one physician trained and experienced in cardiac catheterization present in the room during all catheterization and angiographic procedures.

(b) There shall be at least one registered professional nurse with appropriate training and experience, in accordance with N.J.A.C. 8:33E-1.5(b)4, present in the room during each procedure.

(c) There shall be at least one trained and experienced technician qualified in accordance with N.J.A.C. 8:33E-1.5(b)5 through 8 present in the room during each procedure.

8:43G-7.27 Pilot catheterization program quality improvement

(a) The pilot catheterization program shall include at least the following quality improvement indicators:

1. Low-risk patient mortality and morbidity rate;

2. Physician-specific and overall pilot laboratory percentage of normal studies (not to exceed 25 percent of total annual cases);

3. Increase in the number of normal studies during any reporting period (not to exceed 50 percent, with a plan for corrective action to be submitted to the Department within 60 days should the increase reach 50 percent or more);

4. Percentage of all patients undergoing diagnostic cardiac catheterization in the pilot program who subsequently undergo a therapeutic interventional cardiac procedure as a direct result of the findings of the initial diagnostic procedure; and

5. Clinical appropriateness of the performance of catheterization procedures other than left-heart procedures (that is, right-heart procedures).

8:43G-7.28 Percutaneous transluminal coronary angioplasty policies and procedures

(a) Percutaneous transluminal coronary angioplasty (PTCA) shall be performed only in cardiac surgical centers approved by the New Jersey State Department of Health.

(b) There shall be at least 200 PTCA procedures performed in the hospital per year excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-2.3(d)1.

8:43G-7.29 PTCA staff qualifications

(a) Any physician performing PTCA as primary operator shall meet one of the following qualifications:

1. Is board certified in both internal medicine and the subspecialty of cardiovascular disease, or is board eligible in the subspecialty of cardiovascular disease and shall be examined within two years of initial cardiac eligibility. Physicians meeting either of these qualifications must additionally complete the training and experience requirement in cardiac catheterization including 24 months in the cardiac catheterization laboratory during which time the individual actively participated in at least 200 PTCA's under the supervision of primary operators provided by no more than two separate institutions; or

2. Is board certified in internal medicine and the subspecialty of cardiovascular disease as of July 1, 1990 and has performed at least 50 PTCA's per year as the primary operator for each of the past two years.

(b) Each physician performing PTCA shall perform a minimum of 75 cases per year or 150 over a two-year period, excluding the first year of practice after training. The physician shall perform at least 50 cases annually as the primary operator.

8:43G-7.30 PTCA staff time and availability

(a) The following staff shall be present for all PTCA procedures:

1. A physician who meets the requirements in N.J.A.C. 8:43G-7.23(a);

2. A registered professional nurse certified in basic cardiac life support, and trained and experienced in cardiac catheterization and PTCA who acts as the circulating nurse; and

3. One of the following individuals:

i. A scrub nurse who is either a registered professional nurse or a licensed practical nurse; or

ii. A technician who has been trained in assisting with cardiac catheterization and PTCA.

8:43G-7.31 PTCA space and environment

There shall be an operating room available for immediate use on-site that complies with criteria established in the hospital's surgery policies and procedures and meets the minimal physical requirements of N.J.A.C. 5:23-3.2(b), any time a PTCA procedure is performed on an elective basis.

8:43G-7.32 Electrophysiology studies staff qualifications

(a) The physician performing electrophysiology studies (EPS) as primary operator shall meet at least one of the following qualifications:

1. Fulfills the criteria of being a catheterizing physician as defined in N.J.A.C. 8:43G-7.15(b)1 or 2; or

2. Is board eligible in the subspecialty of cardiovascular disease and has performed 25 complex cases per year as primary operator for each of the past five years.

(b) The physician performing EPS shall have training and experience in cardiac catheterization and one of the following:

1. At least one additional year of specialized training in EPS and cardiac arrhythmia; or

2. At least five years of experience performing invasive cardiac electrophysiologic studies.

(c) Each physician performing EPS shall perform 50 complex cases per year, 25 of which shall be initial studies.

8:43G-7.33 EPS staff time and availability

(a) The following staff shall be present during all EPS procedures:

1. A physician who meets the requirements in N.J.A.C. 8:43G-7.26(a) and (b);

2. A registered professional nurse certified in basic cardiac life support and trained and experienced in cardiac catheterization and EPS who acts as the circulating nurse; and

3. One of the following individuals:

i. A scrub nurse who is either a registered professional nurse or a licensed practical nurse; or

ii. A technician who has been trained in assisting with cardiac catheterization and EPS.

8:43G-7.34 Board eligibility status

Board eligibility status in the subspecialty of cardiovascular disease shall be of limited duration as defined by the American Board of Internal Medicine.

8:43G-7.35 Pediatric cardiac services standards; scope

In addition to the standards in N.J.A.C. 8:43G-7.1 through 7.34 for adult cardiac services, the following standards in N.J.A.C. 8:43G-7.36 through 7.46 shall apply to separate, designated units or services for pediatric cardiac diagnostic services and pediatric surgical centers.

8:43G-7.36 Pediatric cardiac surgery policies and procedures

(a) At least 150 open and closed heart operations shall be performed in the hospital per year with at least 75 open heart operations performed per year, excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-2.3(b)1.

(b) The hospital shall have in effect policies and procedures which ensure that priority lab services will be available to pediatric cardiovascular patients if medically indicated.

(c) All medical and nursing staff who provide services to pediatric cardiac patients shall have training and experience in pediatrics.

8:43G-7.37 Pediatric cardiac surgery staff qualifications

(a) There shall be a director of the pediatric cardiac surgery service who is board certified in thoracic surgery and has five years prior experience in pediatric cardiac surgery.

(b) Effective July 1, 1990, the surgeon in charge of a pediatric cardiac operation shall be board certified in thoracic surgery, or shall meet current requirements to be examined and shall be examined within two years of eligibility.

(c) The cardiac perfusionist for each pediatric cardiac surgical procedure shall have graduated from an educational program for perfusionists accredited by the Council on Allied Health Education Administration (CAHEA) and be certified by the American Board of Cardiovascular Perfusion; or during each of the past two years, shall have performed at least 30 perfusions as primary operator.

8:43G-7.38 Pediatric cardiac surgery staff time and availability

(a) All staff providing clinical services to the pediatric cardiac surgical patient shall be trained and experienced in pediatric cardiac surgical care.

(b) There shall be at least a ratio of one registered nurse to one patient at all times during the first 24 hours of the patient's stay in the pediatric cardiovascular surgical intensive care service.

(c) For patients who remain in the pediatric cardiovascular surgical intensive care service after 24 hours, there shall be at least a ratio of one registered professional nurse to two such patients with capability to adjust staff levels based on acuity level of patient illness.

(d) An anesthesiologist who is board certified in anesthesia, with additional training in pediatric anesthesiology and experience in pediatric cardiac surgery, shall be responsible for anesthetic management of each pediatric cardiac surgical procedure.

(e) A pediatric cardiologist shall be available in the hospital whenever pediatric cardiovascular surgery is scheduled.

(f) There shall be a physician in the hospital at all times who is able to manage pediatric cardiac emergencies. This physician shall not be assigned to the emergency department at the same time.

(g) Counseling by trained and experienced professionals shall be available to assist pre/post operative pediatric cardiac patients/families to cope with the crisis of illness, adjustment to hospitalization, plans for patient's care post-discharge, or bereavement and loss.

8:43G-7.39 Pediatric cardiac surgery space and environment

The hospital shall designate beds in the cardiac surgical intensive care service, the pediatric surgical intensive care service or the pediatric medical intensive care service for patients from the pediatric cardiac surgical service.

8:43G-7.40 Pediatric cardiac surgery supplies and equipment

(a) There shall be monitoring and treatment equipment available that is appropriate for the pediatric cardiac surgical patient.

(b) The pediatric cardiac surgical intensive care service shall have equipment and staff for at least the following:

1. Hemodynamic and electrocardiogram monitoring;

2. Pacemaker usage;

3. Cardiopulmonary resuscitation;

4. Arrhythmia detection and treatment; and

5. Intra-aortic balloon-assisted circulation.

8:43G-7.41 Pediatric cardiac surgery continuous quality improvement methods

(a) There shall be a program of quality continuous improvement for all services that is integrated into the hospital continuous improvement program and 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.

(b) The continuous quality improvement program for surgery shall include at least:

1. Monitoring the volume of each service provided;

2. Infection and complication rates;

3. The incidence of mortality, morbidity, and other adverse occurrences in each service;

4. Patient factors that affect risk of complications in each service; and

5. Retrospective evaluation of emergency procedures in each service.

8:43G-7.42 (Reserved)

8:43G-7.43 Pediatric cardiac catheterization policies and procedures

(a) Pediatric invasive cardiac diagnostic procedures shall be performed only at pediatric cardiac surgery centers.

(b) The pediatric cardiac catheterization service may share the catheterization laboratory with the adult cardiac catheterization program. However, the staff who participates in the pediatric catheterization shall be trained and experienced in the care of the pediatric cardiac patient and the equipment used shall be appropriate to meet the needs of the pediatric patient.

(c) The pediatric cardiac catheterization laboratory shall perform a minimum of 150 pediatric cardiac catheterizations per year, excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-1.11(d).

8:43G-7.44 Pediatric cardiac catheterization staff qualifications

(a) There shall be a director of the pediatric cardiac catheterization service who is board certified in pediatrics, in the subspecialty of pediatric cardiology, and who has completed at least one year of additional training in an accredited program for interventional pediatric cardiac procedures.

(b) Any physician performing pediatric cardiac catheterization in the pediatric cardiac catheterization laboratory shall be board certified in the subspecialty of pediatric cardiology, or shall meet current requirements to be examined and shall be examined within two years of eligibility.

(c) Each physician performing diagnostic cardiac catheterization without supervision shall have performed at least 50 pediatric cardiac catheterizations as the primary operator. The hospital shall determine policy requiring the minimum number of annual procedures that a physician must perform.

(d) Each physician shall perform a minimum of 50 pediatric procedures per year with a minimum of 100 procedures over a two year period.

8:43G-7.45 Pediatric catheterization continuous quality improvement methods

There shall be a peer review committee for the pediatric cardiac catheterization service that includes at least the director of the pediatric catheterization laboratory, the director of pediatric cardiology, a pediatric catheterization cardiologist, and a non-catheterizing cardiologist. The committee shall review all mortalities, serious complications, and selected procedures done in the pediatric catheterization suite to identify trends and problems in the service. Minutes of these meetings shall be maintained.

8:43G-7.46 Staff qualifications waiver

(a) Exceptions for physicians with hospital privileges to these minimum board certification and training requirements may be granted by the Commissioner or his or her designee upon application by an institution providing acceptable documentation which assures that the physician's qualifications are at a level assuring the level of patient safety intended by the requirements of these rules. As part of the waiver request, the hospital shall provide documentation of the practitioner's qualifications that at a minimum addresses the following:

1. A curriculum vitae which describes the practitioner's academic training and professional experience;

2. Documentation of the volume of procedures that the practitioner has completed on an annual basis;

3. Length of experience in performance of procedure;

4. Current status and future intention to meet the requirements for board-certification; and

5. Documentation of the practitioner's complication rates in performing the procedure for which a waiver is sought.

(b) Additional information may be requested from the hospital by the Department in making a determination or it may obtain the recommendations from the Commissioner's Cardiac Services Advisory Committee.

(c) Waivers may be granted for periods not to exceed three years and are renewable at the discretion of the Commissioner.

SUBCHAPTER 8. CENTRAL SERVICE

8:43G-8.1 Central service policies and procedures

(a) The hospital's central 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 be approved by the hospital's infection control committee.

(b) Policies and procedures for central service shall include at least decontamination and sterilization activities, including receiving, decontamination, storage, cleaning, packaging, disinfection, sterilization, and distribution of reusable items.

(c) All equipment and instruments in the hospital shall be processed according to central service cleaning and sterilization policies and procedures.

(d) Manufacturers' written recommendations for equipment use, testing, and cleaning shall be readily available in central service and in the department where the equipment is used.

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

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

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

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

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

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

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

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; and

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.

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

8:43G-8.2 Central service staff qualifications

(a) There shall be a full-time director or supervisor of central service.

(b) The director or supervisor of central services shall have two years of supervisory experience and shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services.

(c) All personnel involved in sterile processing shall be certified through a national sterile processing program recognized by the New Jersey Department of Health and Senior Services within three years of employment and by August 2, 2009.

(d) Personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection.

8:43G-8.3 Central service staff education and training

(a) Requirements for the central service education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) All new central service employees shall receive on-the-job training on practices and equipment unique to the hospital.

(c) Competency for processing tasks shall be documented annually by the employee's supervisor or by the Director of Central Services

8:43G-8.4 Central service patient services

(a) Entrance to the central service processing and decontamination area shall be restricted to persons attired in hospital-laundered or protective attire, in relation to the purpose and scope of their duties.

1. All personnel performing decontamination, preparation, and assembly shall be provided hospital laundered scrubs.

(b) All reusable patient care items shall be reprocessed according to manufacturers' written recommendations.

(c) There shall be a preventive maintenance program for all patient care equipment processed by central service that includes performance verification records. Preventive maintenance shall be documented and records shall be available for inspection.

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

1. Muslin blends shall not exceed a shelf life of 30 days.

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

(e) If the facility is using an Event Related Sterility program, the process shall:

1. Be approved by the Hospital Infection Control Committee;

2. Have a continuous process improvement plan with monthly audits and documentation of facility compliance including:

i. Proper transportation of sterile product;

ii. Proper storage conditions of sterile product;

iii. Proper rotation of sterile product; and

iv. Maintenance of sterile pack integrity; and

3. Include annual inservice education as part of mandatory Infection Control inservicing.

8:43G-8.5 Single use medical devices and outsourcing

(a) Single use patient care items shall not be reprocessed except under the following conditions:

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

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 Title 21 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and

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

3. 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.

(b) Policies and procedures shall be established following OSHA's Blood Borne Pathogens regulation, 29 CFR § 1910.1030, incorporated herein by reference, as amended and supplemented, for the transport of contaminated equipment to off site reprocessing facilities.

(c) Shared reprocessing by multi-hospital 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 and all sterile processing managers.

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

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

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. 8:43G-8.8(a).

(1) Immediate notification shall be made to the receiving hospital upon a positive biological result.

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

8:43G-8.6 Central service space and environment

(a) Each sterilizer processing area shall have exhaust ventilation to remove heat, moisture and odors without recirculating the exhaust to other areas of the hospital.

(b) Exterior shipment cartons shall not be brought into sterile supply storage or processing areas.

(c) Soiled or contaminated supplies shall be physically separated from those that are clean or sterile.

(d) All work surfaces in central supply shall be cleaned with germicidal disinfectant at the end of each work shift and more frequently as necessary.

(e) An area shall be designated for central supply employees to change their clothing and store personal items.

8:43G-8.7 Use and sterilization of patient care items

(a) Patient care items shall be scrupulously cleaned 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 other than scopes must be sterilized by a process that can demonstrate a sterility assurance level of 10^{-6}.

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 in contact with intact skin, but not with

mucous membranes. Noncritical items require intermediate level disinfection or low-level disinfection.

(b) 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 manufacturers' written recommendations or according to policy established by the hospital's infection control committee.

(c) Reusable linens shall be inspected and delinted in a segregated room with adequate ventilation to prevent excess dust and lint accumulation.

1. An illuminated worktable shall be provided to examine linen used for wrapping sterile supplies for tears, pinholes, and other defects.

2. Reusable linens shall be repaired using a heat patch machine.

(d) Flash sterilization and peracetic acid processes are considered just in time sterilization processes. ("Just in time" means for immediate use only.)

1. Flash sterilization should be used for emergency situations only.

2. All items that are flash sterilized shall be thoroughly cleaned and decontaminated prior to sterilization.

3. All items in each flash sterilization cycle shall be documented**.**

(e) 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 a hospital setting.

(f) There shall be a system for monitoring the processing of all equipment and instruments in the hospital for adherence to central service policies and procedures.

8:43G-8.8 Monitoring the sterilization cycle

(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; and

4. Steam sterilizers - weekly.

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

(c) A biological monitor with live spores shall be performed following repair or breakdown of the equipment in (a) above.

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

(e) A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

1. Each package processed in steam;

2. Each package processed in ethylene oxide;

3. Each package processed in low temperature gas plasma;

4. Each load as directed by the manufacturer for peracetic acid; and

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

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

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

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

8:43G-8.9 (Reserved)

8:43G-8.10 Central service quality improvement methods

There shall be a program of quality improvement for central service that is integrated into the hospital quality improvement program and 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.

8:43G-8.11 Sterilizer patient services

(a) All hinged instruments shall be processed in an open position.

(b) All instruments and equipment shall be visually inspected for cracks, pitting, rust, or any condition that would impede cleaning/sterilization. Defective instruments and equipment shall not be used.

(c) Sterilizers in use shall be cleaned on a scheduled basis.

(d) Sterilizer drains shall be flushed at least weekly, unless otherwise specified by the manufacturer.

(e) Sterilizer door gaskets shall provide effective sealing.

(f) 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 hospital policy whichever is greater.

(g) Instruments and medical devices sterilized by ethylene oxide shall be aerated in a mechanical aerator according to manufacturer’s recommendations, or if these recommendations are not available,

they shall be aerated at 140 degrees Fahrenheit for a minimum of eight hours or at 122 degrees Fahrenheit for a minimum of 12 hours.

(h) An indicating thermometer, accurate to three degrees Fahrenheit, shall be located in all ethylene oxide aeration equipment.

(i) All sterilizers shall be operated and maintained in accordance with the manufacturer's instructions.

8:43G-8.12 and 8:43G-8.13 (Reserved)

SUBCHAPTER 9. CRITICAL AND INTERMEDIATE CARE

8:43G-9.1 Scope

The standards set forth in this chapter shall apply to licensed critical and intensive care beds inclusive of medical, surgical, coronary, pulmonary, cardiovascular, and neurological critical care, but not pediatric or neonatal intensive care.

8:43G-9.2 Critical care structural organizations

(a) There shall be an organizational chart, or alternative documentation, that delineates the lines of authority, responsibility, and accountability of staff in the critical care service.

(b) There shall be a multidisciplinary critical care committee or its equivalent for critical care units that includes representatives of at least the medical and nursing staff. The committee shall discuss issues related to the administration of the critical care practice that will enhance patient care.

(c) Meetings with representatives of critical care medical and nursing personnel, at management and staff levels, shall be scheduled at least four times a year to improve interdisciplinary communication.

8:43G-9.3 (Reserved)

8:43G-9.4 Critical care policies and procedures

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

1. Criteria for admission to and discharge and transfer from the unit;

2. A list of procedures that resident physicians, who are graduates of an accredited medical school participating in an approved training program in a hospital setting, may and may not perform;

3. Infection control protocols;

4. Protocols for transfer and transport of patients within the hospital or from the hospital to another facility including who shall accompany the patient being transferred or transported;

5. A visitors policy that specifies visiting hours and number of visitors permitted each patient at any one time, subject to the discretion of the patient's physician or primary care nurse;

6. A policy on the removal of a patient's life support system;

7. A policy defining the physician, specialist and consulting physician to be called for patient emergencies, including a response time for physicians to respond to patient emergencies;

8. Standing orders for patient emergencies;

9. Policies on involving and communicating with families of patients during the first 24 hours after admission and throughout the patient's stay;

10. The hospital shall have in effect policies and procedures which ensure that priority lab services will be available to critical care patients if medically indicated; and

11. Policies on including the registered professional nurse in discussions and decisions among physicians and families about the use of resuscitation technology on patients in the critical care unit.

8:43G-9.5 Critical care staff qualifications

(a) There shall be a physician director who has clinical responsibility for the care rendered in each critical care unit or combination of critical care units.

(b) The physician director of the critical care unit or combination of units shall be board certified in medicine, anesthesia, or surgery, and/or have completed a formal fellowship program in critical care approved by the specialty board in the individual's primary specialty. In the case of a critical care unit that provides one specialty area of critical care, such as coronary care, the physician director of the unit shall be board certified in that particular specialty or subspecialty.

(c) There shall be a registered professional nurse with administrative responsibility for the critical care unit or combination of units who is accountable for all critical care nursing rendered in the unit or units.

(d) The nursing manager of each unit within the critical care service shall be certified in critical care nursing by the American Association of Critical Care Nurses or have three years of experience in critical care nursing.

(e) Each licensed nurse in the critical care service shall have training in basic cardiac life support.

8:43G-9.6 (Reserved)

8:43G-9.7 Critical care staff time and availability

(a) Nurse staffing shall be determined by the acuity of illness of the patients on the critical care unit.

(b) There shall always be at least one registered professional nurse for every three patients. There shall be the capability to increase nurse staffing to one nurse for every two patients or one nurse per patient based on acuity levels.

(c) There shall be a mechanism in place for the critical care service to have access to nutritional support services for advice on both enteral and parenteral nutritional techniques.

8:43G-9.8 (Reserved)

8:43G-9.9 Critical care patient service

Information and explanation shall be provided to the patient and the patient's family and documented in the patient's record, regarding the patient's condition, equipment, and specific procedures.

8:43G-9.10 (Reserved)

8:43G-9.11 Critical care space and environment

There shall be a handwashing sink that is easily accessible to each patient's bedside.

8:43G-9.12 (Reserved)

8:43G-9.13 Critical care supplies and equipment

(a) Each critical care unit shall be equipped to provide at least:

1. Cardiopulmonary resuscitation, including a defibrillator/monitor and emergency drugs;

2. Airway management, including endotracheal and assisted ventilation;

3. Oxygen delivery systems;

4. Continual electrocardiogram monitoring, including 12-lead electrocardiogram;

5. Emergency temporary cardiac pacing;

6. Titrated therapeutic interventions with infusion pumps;

7. Hemodynamic monitoring capabilities, pulse oximetry and and-tidal carbon dioxide monitoring; and

8. Portable life-support equipment for use in patient transport, both within the hospital and for transfer.

(b) Emergency supplies, as defined by the policies and procedures of the critical care unit, shall be accessible for all patients.

(c) All ventilators in use shall be equipped with an integral minimum ventilation pressure (disconnect) alarm.

(d) There shall be a system for obtaining immediate emergency replacement or repair of equipment in the critical care service.

8:43G-9.14 Critical care staff education

Requirements for the critical and intermediate care staff education and training program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-9.15 (Reserved)

8:43G-9.16 Critical care continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the critical care service that is integrated into the hospital continuous quality improvement program and 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.

(b) The continuous quality improvement activities of the critical care service shall include maintaining data on mortality rates, complications, and patients readmitted to the hospital and critical care unit with the same diagnosis during a specified interval of time.

(c) Continuous quality improvement program for the critical care service shall include review of cases involving removal of life support.

8:43G-9.17 (Reserved)

8:43G-9.18 Intermediate care standards; scope

The standards set forth in N.J.A.C. 8:43G-9.19 through 9.25 shall apply to designated medical, surgical, coronary, pulmonary, cardiovascular, and neurological beds providing intermediate care, but not pediatric or neonatal intermediate care.

8:43G-9.19 Intermediate care structural organization

(a) Intermediate care services shall be provided in all hospitals that provide critical care services.

(b) Dedicated intermediate care beds shall be provided within an identifiable patient care nursing unit. There shall be a separate physical area devoted to nursing management for the care of the intermediate patient. This separate area may be designated within an existing nursing station located on the intermediate nursing care unit.

8:43G-9.20 Intermediate care policies and procedures

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

1. Criteria for admission to the service;

2. Criteria for discharge and transfer from the service to other patient care units in the hospital;

3. Criteria for discharge from the service to other health care facilities;

4. The number or percentage of beds on the service that provide continuous electrocardiogram monitoring;

5. The frequency with which physicians must visit their patients on the unit; and

6. Acuity assignments made on a daily basis for patients in each intermediate care unit with the minimum average ratio of one nurse to every six patients.

(b) There shall be a clearly defined protocol for medical administration of the service to ensure the monitoring and enforcement of the service's criteria for admission, transfer, and discharge.

(c) The intermediate care nursing staff shall be represented on the critical care committee or its equivalent, and, if pediatric or coronary patients are cared for by the intermediate care service, intermediate care nursing staff shall be represented on the committees responsible for developing policies and procedures for pediatric care and coronary care.

8:43G-9.21 Intermediate care staff qualifications

There shall be a physician director of the intermediate care service who is board certified in internal medicine, anesthesiology, or surgery, and/or has completed a formal fellowship program in critical care approved by the specialty board in the individual's primary specialty. In the case of a unit that provides one specialty area of intermediate care, such as coronary care, the physician director of the unit shall be board certified in that particular specialty or subspecialty. The physician director of the intermediate care service may also be the physician director of another service.

8:43G-9.22 (Reserved)

8:43G-9.23 Intermediate care staff education and training

Requirements for the intermediate care services staff education and training program shall be as provided at N.J.A.C. 8:43G-5.9.

8:43G-9.24 Intermediate care continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the intermediate care service that is integrated into the hospital continuous quality improvement program and 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.

(b) The continuous quality improvement activities of the intermediate care service shall include collecting and maintaining data on patient acuity and patient mix.

SUBCHAPTER 10. DIETARY

8:43G-10.1 Dietary policies and procedures

(a) The dietary service shall have written policies and procedures for all dietary services that are reviewed at least once every three years, revised more frequently as needed, and implemented.

(b) A diet manual detailing nutritional and therapeutic standards for meals and snacks, and a nutrient analysis of menus, shall be annually reviewed. A current diet manual shall be available at each nurses station and in the dietary department and medical library.

(c) There shall be a policy to promote the participation of the dietary service in meetings of multidisciplinary health care teams to assess patients.

8:43G-10.2 (Reserved)

8:43G-10.3 Dietary staff qualifications

(a) There shall be a food service director who has a baccalaureate degree from an accredited college or university in food, nutrition, food services management, or a related area, or has at least four years of experience in food services management in a health care facility and successful completion of Food Management Certification (FMC) and Dietetic Assistant programs or their equivalents.

(b) A registered dietitian shall have full-time responsibility for the clinical aspect of the dietary service.

8:43G-10.4 Dietary staff time and availability

(a) A dietitian shall be on duty in the hospital for a specified period, as determined by the hospital, during every 48-hour weekend or holiday period.

(b) Dietary service members shall be assigned duties based upon their education, training and competencies and in accordance with their job descriptions.

8:43G-10.5 (Reserved)

8:43G-10.6 Dietary patient services

(a) All new admissions shall be listed with the dietary service by the first pre-meal deadline following admission, as specified in the dietary service's policies and procedures.

(b) Each patient's diet shall be documented in the medical record.

(c) A physician shall write a specific dietary order for each patient.

(d) Patients shall be screened for nutritional assessments based on specific criteria. Nutritional assessments for patients determined to be at nutritional risk shall be completed within 72 hours of admission.

(e) The dietary service shall set guidelines for subsequent nutritional assessments of patients determined to be at nutritional risk.

(f) Patients' nutritional needs for food and food supplements shall be met, in accordance with physician orders.

(g) All diets shall conform to the hospital's diet manual.

(h) At least three meals shall be served daily, and no more than 15 hours shall elapse between dinner and breakfast.

(i) Nourishment shall be available between meals and at night.

(j) Food production shall be sufficient in quantity to meet nutritional needs and shall be coordinated with dietary orders.

(k) Physician orders and changes in physician orders for diets shall be effected by the next mealtime, if they are received by the dietary services by the pre-meal deadline specified in the dietary service's policies and procedures.

(l) The dietary service shall follow the policies and procedures developed by the pharmacy and therapeutics committee regarding possible food/drug interactions.

(m) There shall be a mechanism for evaluating patients on each nursing unit to ensure they are being adequately nourished. This may involve rounds, review of charts, plate waste measurement, or multidisciplinary team conferences.

(n) There shall be a mechanism for the dietary service to be informed if the patient does not receive the diet that has been ordered, or is unable to consume the diet.

(o) There shall be a mechanism for patients and their families to interact with the dietary service, such as a written comment sheet, patient rounds, or distribution of the dietary service's phone number.

(p) Patients with special dietary needs, based on criteria established by the hospital, shall receive dietary instruction from a dietician or authorized designee during hospitalization.

(q) The dietary service shall comply with the requirements of Chapter XII of the New Jersey State Sanitary Code, "Sanitation in Retail Food Establishments and Food and Beverage Vending Machines" (N.J.A.C. 8:24).

8:43G-10.7 (Reserved)

8:43G-10.8 Dietary staff education and training

Requirements for the dietary education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-10.9 (Reserved)

8:43G-10.10 Dietary continuous quality improvement methods

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

(b) Patient satisfaction shall be monitored on an ongoing basis, and a survey mechanism shall be in place that produces quarterly summaries.

(c) As part of its quality assurance activities, the dietary service shall maintain a log detailing problem identification, action, and follow-up.

(d) There shall be a system in place to ensure the accuracy of dietary orders that are transmitted to the dietary service. This system shall be monitored as part of the quality assurance program.

SUBCHAPTER 11. DISCHARGE PLANNING

8:43G-11.1 Discharge planning structural organization

(a) Each hospital shall have a discharge planning program with formal mechanisms in place which include criteria by which every patient is screened for post-discharge needs.

(b) The hospital shall maintain an organizational chart or alternative documentation that clearly delineates the responsibilities, authority, and accountability of the discharge planning program staff.

8:43G-11.2 (Reserved)

8:43G-11.3 Discharge planning policies and procedures

Hospital staff working in the discharge planning program shall have open access to relevant patient records.

8:43G-11.4 Discharge planning staff qualifications

(a) A team that includes at least a social worker and a registered professional nurse shall have responsibility for and guide multidisciplinary discharge planning for patients who, upon screening, are determined to require coordinated discharge planning. This team shall receive input from, and communicate with, the patient's attending physician, staff nurse or nurses, and other health professionals.

(b) The social worker and registered nurse who are members of the discharge planning team shall have received education or training in hospital discharge planning.

8:43G-11.5 Discharge planning patient services

(a) Patients who require post-discharge continuity of care shall be linked to needed resources, such as:

1. Placement in a nursing home;

2. Enrollment with a home care program;

3. Transfer to another health care facility;

4. Referral to community resources; or

5. Information regarding availability of Medicare or Medicaid benefits.

(b) The hospital shall make a diligent effort to find and effect an appropriate placement for any patient ready for discharge but requiring further care. Documentation shall be included in the patient's medical record.

(c) Patient care conferences or discharge planning rounds shall be held to discuss planning for patients needing continuity of care.

(d) The patient shall participate in the development of the discharge plan, where possible. The family or significant other shall participate in the development of the plan, where possible, and when the patient is able to agree, and does agree, to their involvement.

(e) Discharge planning shall be initiated within 24 hours of admission in accordance with N.J.A.C. 8:43G-18.5(d) and 33.2(c). If a patient's needs for post-discharge care change after a discharge plan is developed, the plan shall be modified to meet the patient's needs.

(f) The hospital shall have a mechanism to ensure that each patient receives, upon discharge, written instructions about follow-up care and medications, if relevant, and the telephone number of a contact person to call in case he or she has questions after discharge.

(g) For all patients who receive discharge planning, the patient's medical record shall include on-going documentation and a summary or summaries of the patient's discharge plan prepared by a member of the discharge planning team at the time of discharge, or within 30 days of discharge.

8:43G-11.6 Discharge planning continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for discharge planning that is integrated into the hospital continuous quality improvement program and 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. The program shall monitor at least:

1. That communication occurs among members of the multidisciplinary team, and the patient and family;

2. Appropriateness of referrals; and

3. Implementation of the discharge plan.

(b) There shall be a mechanism in place for monitoring the effectiveness of the discharge planning process on a periodic basis.

SUBCHAPTER 12. EMERGENCY DEPARTMENT AND TRAUMA SERVICES

8:43G-12.1 Emergency department structural organization

The hospital shall provide emergency services on a 24 hour basis, unless it is a licensed special or psychiatric hospital. Special and psychiatric hospitals shall have a written plan and a system to meet medical emergencies based on the types of patients and cases that are typically treated in the hospital. Those hospitals exempted under this section shall not offer emergency medical services to the general public.

8:43G-12.2 Emergency department policies and procedures

(a) The emergency department shall have written policies and procedures for medical, trauma, and pediatric patients, that are reviewed at least once every three years, revised more frequently as needed, and implemented.

(b) Each hospital shall develop and implement policies and procedures for the evaluation and treatment by qualified medical personnel of all patients who come to the emergency department. An advanced practice nurse functioning as qualified medical personnel evaluating and treating patients in the emergency department shall establish and maintain a collaborative relationship, described in these policies and procedures, with an emergency physician regularly practicing in that hospital's emergency department. A physician assistant functioning as qualified medical personnel evaluating and treating patients in the emergency department shall be supervised by an emergency physician regularly practicing in that hospital's emergency department. Emergency physicians shall meet the qualifications required in N.J.A.C. 8:43G-12.3(b).

(c) There shall be a transfer protocol that governs interhospital transfers of patients, including but not limited to pediatric and trauma patients, in need of specialized care not provided in the hospital. Transfer protocols for trauma patients shall be in accordance with N.J.A.C. 8:43G-12.15(c) through (g).

(d) The emergency department shall have a written protocol that governs the management of psychiatric patients who require special services not available in the hospital. This protocol addresses the roles and involvement of hospital health professionals, social work services, law enforcement officials, and mental health services, when indicated.

(e) The emergency department shall have a written protocol that addresses the ability of family members and significant others to remain with patients during treatment. The protocol shall also address the special needs of patients who are unable to communicate for reasons of language, disability, age, or level of consciousness.

(f) The emergency department shall have a written protocol that governs referrals if a clinical speciality service is not available.

(g) The emergency department shall have policies to ensure compliance with regulations at 42 CFR 489.24 and 42 CFR 489.20 requiring examination and treatment for emergency conditions and women in labor.

(h) The emergency department shall have written policies for airway maintenance, adult and pediatric sedation, analgesia, and rapid sequence intubation.

(i) The hospital shall maintain a trauma registry in accordance with N.J.A.C. 8:43G-12.21() and (c).

8:43G-12.3 Emergency department staff qualifications

(a) There shall be a physician director of the emergency department who is board certified in emergency medicine or who has five years of full-time experience in emergency medicine, which may include three years residency in emergency medicine, within the past seven years.

(b) Each physician practicing in the emergency department, except residents functioning under supervision as part of the hospital's graduate residency training program, consulting physicians, and private physicians who are attending to their patients in the emergency department, shall meet at least one of the following qualifications:

1. Board certification in emergency medicine;

2. Successful completion of an approved residency program in emergency medicine, family medicine, general internal medicine, general surgery, or general pediatrics; or

3. Three years of full-time clinical experience in emergency medicine within the past five years.

(c) Each physician practicing in the emergency department, except residents functioning under direct supervision as part of the hospital's graduate residency program, consulting physicians, and private physicians who are attending to their patients in the emergency department, shall attain provider status in Advanced Cardiac Life Support and either Advanced Pediatric Life Support or Pediatric Advanced Life Support within 12 months of initial assignment, and shall continuously maintain this status thereafter. Physicians who are board certified in emergency medicine shall be exempt from this requirement.

(d) Each physician practicing in the emergency department, except residents functioning under direct supervision as part of the hospital's graduate residency program, consulting physicians, and private physicians who are attending to their patients in the emergency department, shall attain provider status in Advanced Trauma Life Support within 12 months of initial assignment, and shall continuously maintain this status thereafter. Physicians who are board certified in emergency medicine shall be exempt from this requirement.

(e) The emergency department shall be staffed at all times by at least one professional nurse who has attained and continuously maintains provider status in Advanced Cardiac Life Support.

(f) The emergency department shall comply with the provisions of N.J.A.C. 8:41-7.4 in the utilization of paramedics.

(g) All registered professional nurses regularly assigned to the emergency department shall be trained and have completed courses in emergency care, including at least:

1. Basic life support (CPR);

2. Advanced Cardiac Life Support (ACLS), with ACLS provider status attained within 12 months of initial assignment and continuously maintained thereafter;

3. A minimum of eight contact hours of education every two years in basic trauma assessment, intervention, and stabilization; and

4. Pediatric Advanced Life Support (PALS), or Advanced Pediatric Life Support (APLS), or Emergency Nurse Pediatric Course (ENPC), with PALS or APLS or ENPC provider status attained within 12 months of initial assignment and continuously maintained thereafter.

8:43G-12.4 Additional pediatric requirements

(a) Each emergency department shall have a designated pediatric liaison physician and a designated pediatric liaison nurse, who shall be responsible for review and approval of the emergency department's pediatric activities, including:

1. Policies and procedures for pediatric care;

2. Pediatric equipment;

3. Continuous quality improvement for pediatric patients;

4. Staff training and education for pediatric care; and

5. Pediatric emergency medicine registry.

(b) Upon 60 days notice by the Department, each emergency department shall implement and maintain a pediatric emergency medicine registry for all emergency department admissions under 18 years of age who either die or are admitted to an intensive care unit or step-down unit. This registry shall include the following data items:

1. Medical record number;

2. Hospital identifier number (assigned randomly);

3. Date of service;

4. Gender;

5. Date of birth (not age);

6. Zip code;

7. Baseline medical condition;

8. Mode of arrival;

9. Pre-hospital medical and/or procedural interventions, including emergency medical services times and vital signs;

10. Nature of presenting illness;

11. Physician professional characteristics (for example, board certification or other special training);

12. Chief complaint category;

13. Initial vital signs upon presentation;

14. Emergency department medical and/or procedural interventions (treatment rendered);

15. Clinical impression;

16. Time of call for transfer;

17. Mode of transport on transfer;

18. Transport team interventions;

19. Intensive care unit number;

20. Intensive care unit physician professional characteristics (for example, board certification or other special training);

21. Medical and/or procedural interventions during first hour in intensive care unit;

22. Initial critical care score;

23. Length of stay in intensive care unit;

24. Final disposition;

25. Functional neurologic status; and

26. Functional physiologic status.

(c) Based upon recommendations from the New Jersey Emergency Medical Services for Children Advisory Council, the Department may require, through promulgation of an amendment to (b) above, the inclusion of additional data items.

(d) Registry data shall be submitted on an annual basis to the Department in a form prescribed by the Department.

8:43G-12.5 Emergency department staff time and availability

(a) At all times at least one licensed physician who meets at least one of the qualifications in N.J.A.C. 8:43G-12.3(b) shall be present in the emergency department to attend to all emergencies.

(b) There shall be a physician specialist on call to the emergency department for each major clinical service provided by the hospital, including a physician who is credentialed by the hospital to care for children and who is either board certified in pediatrics or has attained provider status in Advanced Pediatric Life Support or Pediatric Advanced Life Support.

1. The hospital emergency department shall comply with the requirements set forth in N.J.A.C. 8:43G-5.1(l)2 for all emergency department patients deemed by a hospital clinical provider to require emergent care, regardless of whether the patient lacks a primary care physician. In addition, the hospital clinical provider making that judgment shall make a determination as to whether the responding on-call physician may be a resident or, rather, the emergency requires a physician who has completed all residency requirements.

2. A standing transfer agreement with a facility that can provide an appropriate level of care for pediatric patients may be substituted for the on-call physician credentialed and qualified to care for children if the hospital does not have the capability of providing such a physician for on- call duty.

(c) At least one registered professional nurse who has successfully completed the Emergency Nursing Pediatric Course, Advanced Pediatric Life Support or Pediatric Advanced Life Support shall be present at all times in the emergency department. The hospital shall have in place a protocol to increase nurse staffing based on volume and acuity.

8:43G-12.6 Definitions

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

"Comes to the emergency department" means, with respect to an individual requesting examination or treatment by him or herself or with another person, that the individual is on hospital property (including ambulances owned and operated by the hospital even if the ambulance is not on hospital grounds). An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the emergency department.

"Emergency department" means, an organized clinical department of the hospital which, at a minimum, evaluates and treats emergency medical conditions.

"Emergency medical condition" means:

1. A medical condition manifesting itself by acute symptoms or sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that absence of immediate attention could reasonably be expected to result in:

i. Placing the health of the individual (or, with respect to a pregnant woman the health of the woman or her unborn child) in serious jeopardy;

ii. Serious impairment to bodily functions; or

iii. Serious dysfunction of a bodily organ or part; or

2. With respect to a pregnant woman who is having contractions:

i. That there is inadequate time to effect a safe transfer to another hospital before delivery; or

ii. That transfer may pose a threat to the health or safety of the woman or the unborn child.

"Medical screening examination" means an examination and evaluation within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, performed by qualified medical personnel (as defined below and specified by hospital by-laws or policies and procedures) to determine whether or not an emergency medical condition exists.

"Qualified medical personnel" means a physician who meets the requirements at N.J.A.C. 8:43G-12.3, or an advanced practice nurse certified by the New Jersey State Board of Nursing, or a physician assistant licensed by the New Jersey State Board of Medical Examiners. The advanced practice nurse or licensed physician assistant shall have training and experience in emergency care.

"Stabilize" means to provide such medical treatment of an emergency medical condition that is necessary to assure within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that the woman has delivered the child and the placenta.

8:43G-12.7 Emergency department patient services

(a) When an individual comes to the emergency department requesting examination or treatment for a medical condition, or if a request is made on the individual's behalf, clinical priority for treatment shall be assigned by a registered professional nurse or qualified medical personnel.

(b) Treatment for life-threatening emergencies shall be initiated immediately.

(c) If an individual comes to the emergency department requesting examination or treatment for a medical condition, or if a request is made on the individual's behalf, the hospital shall provide for an appropriate medical screening examination performed by qualified medical personnel. Medical screening may be provided in the emergency department or urgent care clinic or area accessible to the emergency department and on hospital grounds.

(d) If it is determined that an emergency medical condition exists, the patient must be evaluated by a physician and provided with such medical treatment as is necessary to assure that the condition has been stabilized, except as provided in (e) below.

(e) If a patient has an emergency medical condition which has not been stabilized, the hospital shall not transfer the patient unless:

1. The patient (or a legally responsible person acting on the patient's behalf), after being informed of the hospital's obligations under this section and of the risk of transfer, in writing requests transfer to another medical facility; or

2. A physician has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the patient and, in the case of labor, to the unborn child, from effecting the transfer. This certification shall include a summary of the risks and benefits upon which the certification is based.

(f) If it is determined that an emergency medical condition does not exist, the patient shall either be treated in the emergency department or shall be referred to an appropriate health care facility or provider; and the patient shall be discharged in accordance with (n) below.

(g) No patient who comes to the emergency department shall be discharged to home or another facility without being seen and evaluated by qualified medical personnel. This evaluation shall occur within four hours of the patient's coming to the emergency department.

(h) The hospital shall implement a protocol for meeting the needs of patients in a timely manner, such as augmenting staff and notifying or diverting ambulances when a specified volume of patients in the emergency department is reached, or patient waiting time before initial evaluation by qualified medical personnel exceeds four hours.

(i) The emergency department shall have a written protocol for the care and disposition of patients who stay in the department for protracted periods of time, for example, in awaiting inpatient beds. This protocol shall address areas such as patient monitoring, patient privacy, provision for family members or significant others, and the active seeking of inpatient beds or transfer by emergency department staff.

(j) A patient shall be transferred from the emergency department to the in-patient service of the hospital, to a facility that provides care unavailable at the hospital, or discharged to home no more than 12 hours after the patient is initially treated on an emergency basis or is stabilized. Exceptions to the 12 hour requirement shall pertain when:

1. Test results are pending and will be used to determine discharge action;

2. The patient is under clinical observation; or

3. The patient is waiting after transport has been summoned.

(k) The hospital shall maintain documentation in all cases in which patients are retained for more than 12 hours in the emergency department.

(l) No patient for whom inpatient admission is required shall be held under clinical observation in the emergency department for more than eight hours if a bed is available in an inpatient unit that has the correct monitoring equipment or can meet the needs of the patient.

(m) A registry of all individuals who come to the emergency department shall be maintained that includes the patient name and a least:

1. Medical record number;

2. Date and time arrived. After December 20, 2000, the names of the ambulance provider and mobile intensive care unit provider, if applicable, shall be entered in the registry;

3. Time discharged;

4. The name(s) of qualified medical personnel who provided the emergency medical screening examination;

5. The name(s) of treating qualified medical personnel;

6. Chief complaint and/or medical diagnosis; and

7. Disposition of the patient.

(n) Upon discharge from the emergency department following a medical screening examination and/or treatment, the patient or his or her representative shall be given written instructions and an oral explanation of those instructions. Documentation of instructions, the name of the physician who ordered the instructions, the name of the person who gave the oral explanation, and the name of the person receiving the instructions shall be entered legibly in the medical record.

(o) Patients requiring post-discharge care shall be referred after clinical evaluation to needed health care or health-related resources. The hospital shall provide assistance, such as referral to the social work department, to a patient requiring assistance in obtaining needed services.

(p) A patient shall be transferred to another health care facility only for a valid medical reason or by patient choice. The sending emergency department shall receive approval from a physician and the receiving health care facility before transferring the patient. Documentation for the transfer shall be sent with the patient, with a copy or summary maintained by the transferring hospital. This documentation shall include at least:

1. Informed consent of the patient or responsible individual, if possible;

2. Reason for transfer;

3. Signature of the physician who ordered the transfer;

4. Condition of the patient upon transfer;

5. Patient information collected by the sending emergency department, including x-ray films or written interpretation by a radiologist; and

6. Name of the contact person at the receiving hospital.

(q) Documentation of a patient's transfer sent by the transferring hospital shall be a permanent part of the patient's medical record at the receiving hospital.

(r) A medical record shall be established and maintained for each patient treated in the emergency department and include at least:

1. Mode, date and time of arrival. After (one year after the adoption of these rules), the names of the ambulance provider and mobile intensive care unit provider, if applicable, and copies of all available prehospital care records shall be entered in the patient's emergency department medical record;

2. Allergies, including allergy to latex;

3. Medications used before coming to the emergency department;

4. Immunizations when relevant;

5. Timed vital signs;

6. Chief complaint;

7. Physician assessment;

8. Nursing assessment;

9. Treatment rendered, signed by the person who rendered the treatment;

10. Medications prescribed and administered while in the emergency department signed by the person who prescribed and the person who administered the medications;

11. Discharge instructions;

12. Last menstrual period, if relevant;

13. Whether the patient visited the emergency department within the previous 72 hours;

14. Age and sex of the patient; and

15. Transfer information, such as destination facility and reason for transfer.

(s) Deceased patients shall be removed from rooms occupied by other patients, when possible, or shall be curtained off. The deceased shall be transported in the hospital and removed from the hospital in a dignified manner.

(t) The emergency department staff shall conform with hospital policies and procedures for complying with applicable statutes and protocols to report child abuse, sexual abuse, and abuse of elderly or disabled adults, specified communicable disease, rabies, poisonings, and unattended or suspicious deaths.

(u) The emergency department shall be prepared to communicate and shall communicate with emergency medical services regarding patients about to arrive by emergency vehicles. The department shall be prepared to receive such patients when they arrive.

(v) The phone number of the designated regional or Statewide New Jersey Poison Information and Education System (1-800-962-1253) shall be posted in the emergency department.

(w) Radiology services for emergency needs shall be available to the emergency department 24 hours a day.

(x) Clinical laboratory services for emergency needs shall be available to the emergency department 24 hours a day.

(y) The emergency department shall have access to and utilize a record of hospital employees, medical staff members, and volunteers who can provide interpretive services to patients as required at N.J.A.C. 8:43G-5.5(c).

(z) Security personnel shall be available to the emergency department when needed.

8:43G-12.8 (Reserved)

8:43G-12.9 Emergency department space and environment

(a) The emergency department shall meet criteria established by the Federal Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1987 Edition, section 7.9, or later edition, if in effect, which are hereby incorporated by reference.

(b) The emergency department shall have the necessary monitoring devices, supplies, and equipment to meet the needs of patients of all ages. Availability of pediatric equipment shall be in accordance with "Guidelines for Pediatric Equipment and Supplies for Emergency Departments," Committee on Pediatric Equipment and Supplies for Emergency Departments, National Emergency Medical Services for Children Resource Alliance, 31 Annals of Emergency Medicine 54, January, 1998, published by ACEP, PO Box 619911, Dallas, TX 75261-9911, (972) 550-0911, (800) 798-1822, incorporated herein by reference.

(c) The emergency department shall be equipped to stabilize all patients.

(d) The emergency department shall be equipped with, at least, patient monitoring equipment and resuscitation equipment.

(e) The emergency department shall have a functioning two way communications system operating on an assigned frequency of 155.340 MHz for communicating with ambulance services about arriving patients.

8:43G-12.10 Emergency department staff education and training

(a) Requirements for the emergency department education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) Regularly assigned emergency department staff shall attend training or educational programs related to the identification and reporting of child abuse and/or neglect in accordance with N.J.S.A. 9:6-1 et seq.; sexual abuse; domestic violence; and abuse of the elderly or disabled adult.

8:43G-12.11 Emergency department continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the emergency department that is integrated into the hospital continuous quality assurance program and 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.

(b) The continuous quality improvement program shall include periodic collection of emergency department data in at least the following areas:

1. Waiting time;

2. Appropriateness and timeliness of transfers;

3. Provision of written instructions;

4. Timeliness of diagnostic studies;

5. Appropriateness of treatment rendered;

6. Unscheduled revisits within 72 hours for the same condition;

7. Mortality; and

8. Care of patients who are retained in the emergency department for long periods of time.

(c) Continuous quality improvement shall include review of selected medical charts for both adult and pediatric patients.

(d) The quality assurance program shall assess whether physicians, including residents, are on duty for periods of time that have an adverse effect on patient care.

8:43G-12.12 Trauma services; scope and purpose

(a) The requirements of N.J.A.C. 8:43G-12.12 through 12.23 shall apply to all hospitals designated by the Department of Health as Level I or Level II trauma centers, pursuant to Certificate of Need designation criteria at N.J.A.C. 8:33P.

(b) The purpose of the rules designated in (a) above is to specify the personnel, organization and other resources required for hospitals designated and licensed as trauma centers, and to delineate the joint responsibilities of community hospital emergency departments and trauma centers in the treatment of trauma patients.

8:43G-12.13 Trauma services; definitions

The following words and terms, when used in N.J.A.C. 8:43G-12.12 through 12.23, shall have the following meanings, unless the context clearly indicates otherwise:

"Advanced life support" means an advanced level of prehospital, interhospital, and emergency service care which includes basic life support functions, cardiac monitoring, cardiac defibrillation,

telemetered electrocardiography, intravenous therapy, administration of specific medications, drugs and solutions, use of adjunctive ventilation devices, trauma care, and other techniques and procedures authorized by the Commissioner.

"Basic life support" means a level of prehospital care which includes patient stabilization, airway clearance, external closed chest cardiopulmonary resuscitation, control of hemorrhage, initial wound care, fracture stabilization, victim extrication, and other techniques and procedures authorized by the Commissioner.

"Commissioner" means Commissioner of Health and Senior Services.

"Department" means New Jersey Department of Health and Senior Services.

"Emergency medical technician" (EMT) means an individual who has completed a course of instruction and who has been issued certification by the Commissioner to provide basic life support services, in accordance with N.J.A.C. 8:41.

"In-hospital" means present at all times and immediately available to the trauma center. On call personnel are not considered to be in-hospital.

"Major trauma" means an injury to a trauma patient who sustains a sudden injury, due to violence or other forces, that requires medical/surgical intervention to prevent death or disability. Patients included are those with both injuries in the ICD-9 CM diagnosis or injury code range of 800.00 through 959.9 and an associated E (external cause of injury) code, with the exception of drowning or suffocation. Patients must also meet, as a result of such injury rather than another disease or condition, one or more of the following criteria:

1. Transfer to a designated trauma or burn center from a community hospital;

2. Admission to intensive or critical care or another monitored setting;

3. Hospitalization for three or more days;

4. Injury score of 3 or more on the Abbreviated Injury Scale;

5. Survival probability of 90 percent or less according to the Trauma Score/Injury Severity Score (TRISS) method; or

6. Death (including deaths in the emergency department).

"Medical control" means direction by a hospital-based physician of basic and/or advanced life support services delivered in the field by authorized personnel from a licensed emergency department.

"Mobile intensive care unit (MICU) means a specialized emergency medical service vehicle staffed by mobile intensive care paramedics or mobile intensive care nurses trained in advanced life support nursing and operated for the provision of advanced life support services under the direction of an authorized hospital, in accordance with the provisions of N.J.A.C. 8:41.

"On call" means that personnel are responsible for attendance at the trauma center when their presence is required. An on call roster shall be maintained for scheduling these personnel.

"Promptly available" means that personnel can be attending patients at the trauma center within a maximum of 30 minutes from the time they are called.

"Trauma" means a physical wound or injury.

8:43G-12.14 Trauma services structural organization

(a) Hospitals designated as Level I or Level II trauma centers shall have organized departments or services for the following specialties:

1. General surgery;

2. Neurologic surgery;

3. Orthopedic surgery;

4. Emergency services; and

5. Anesthesia.

(b) Hospitals designated as Level I trauma centers shall maintain a volume of at least 600 major trauma cases per year. Level II trauma centers shall maintain a volume of at least 350 major trauma cases per year.

(c) Only a hospital which has been designated by the Department as a Level I or Level II trauma center may use the terms "Trauma Center," "Trauma service," "Trauma Unit," "Trauma Facility," "Trauma Program," "Trauma Hospital," or any similar terms in advertising or marketing materials, or may in any other way hold itself out to the public as providing trauma services of the type offered by Level I or Level II trauma centers, as described in this subchapter.

8:43G-12.15 Trauma services policies and procedures

(a) The trauma 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 ensure a systematic and comprehensive approach to the care of trauma patients and shall include at least:

1. Trauma patient triage protocols;

2. Trauma team response protocols;

3. Trauma patient resuscitation and stabilization protocols;

4. Operating room protocols, including priority status for trauma patients, as required by N.J.A.C. 8:43G-12.19;

5. Trauma patient transport protocols;

6. Bypass and diversion protocols ensuring that major trauma patients are not diverted unless needed to ensure patient safety; and

7. Monitoring and evaluation of trauma patients throughout their hospital stay.

(b) In hospitals that are designated as a Level I or Level II trauma center, the emergency department and the trauma center shall jointly develop policies and procedures to ensure coordination and quality of care to trauma patients.

(c) All other hospitals shall develop inter-hospital transfer agreements and protocols in cooperation with, at a minimum, the designated regional Level I trauma center and the nearest designated Level II trauma center. These protocols shall be consistent with Federal regulations at 42 CFR 489.24 and shall include, at a minimum:

1. Clinical criteria for transfer consistent with the capacity of the referring hospital; and

2. Responsibilities of the transferring and receiving physicians, including:

i. The responsibility of the transferring physician to select the appropriate facility, stabilize the patient, and initiate transfer;

ii. Consultation with the receiving physician regarding pre-transfer diagnostic procedures and selection of mode of transport, equipment, and personnel needed to manage patient care during transport;

iii. The responsibility of the receiving physician to ensure capability to provide needed care and document approval for the transfer; and

3. Policies and procedures that ensure the availability of a trauma patient transport system which includes, at a minimum, a transport team staffed by health professionals with special training in trauma care in accordance with hospital policy.

(d) Each emergency department and designated trauma center shall have a written transfer agreement with an organized burn unit or center, with clinically appropriate criteria for safe transfer of patients who require specialized burn treatment.

(e) Each emergency department and designated trauma center shall have a written transfer agreement with a New Jersey hospital designated as a regional perinatal center, with clinically appropriate criteria for safe transfer of patients who require specialized perinatal or neonatal services.

(f) Each hospital and trauma center shall have a written transfer agreement with a comprehensive rehabilitation hospital to assure continuity of care for patients who may require inpatient comprehensive rehabilitation.

(g) Each Level II trauma center shall have a transfer agreement with a regional Level I New Jersey trauma center.

8:43G-12.16 Trauma services staff qualifications

(a) There shall be a physician director of trauma services who is board certified in surgery, and who has also completed the following post-residency clinical experience in trauma services (which may include experience in a trauma or surgical critical care fellowship program) at a center equivalent to Level I or Level II-trauma center:

1. For Level I trauma centers, at least five years experience; and

2. For Level II centers, at least three years experience.

(b) Clinical privileges for practitioners in the trauma service shall be specifically delineated by the hospital-medical staff in consultation with the physician director of trauma services, and shall include such criteria as board certification, Advanced Trauma Life Support certification, trauma-related continuing medical education, and volume.

(c) There shall be a trauma nurse coordinator whose responsibilities include at least:

1. Mobilizing qualified nursing personnel from inpatient units as needed for emergency situations; and

2. Overall coordination and integration of the trauma service with other services in the hospital.

(d) All registered professional nurses regularly assigned to trauma resuscitation shall be trained in trauma care, including at least:

1. Compliance with each of the training requirements for emergency department nurses listed in N.J.A.C. 8:43G-12.3(g); and

2. Completion of the Trauma Nurse Core Course taught by the Emergency Nurses Association within 12 months of initial assignment, followed by a minimum of eight contact hours of education every two years in trauma assessment, intervention, and stabilization.

8:43G-12.17 Trauma services staff time and availability

(a) For Level I and Level II trauma centers there shall be present in-hospital at all times personnel who meet the following qualifications:

1. At least one general surgeon who is credentialed to provide trauma care and, in consultation with the chief of neurosurgery, credentialed to initiate neurosurgical stabilization of patient; and

2. An emergency physician in accordance with requirements at N.J.A.C. 8:43G-12.3, who is credentialed in accordance with N.J.A.C. 8:43G-12.16(b); and

3. Anesthesia personnel in accordance with requirements at N.J.A.C. 8:43G-6.3.

(b) For Level II trauma centers only, the in-hospital requirements specified in (a)l or 2 above may be fulfilled by senior residents (post-graduate year 4 or 5) in the hospital's accredited surgical training program who are credentialed for trauma surgery by the physician director of the trauma service. When a senior resident is used to fulfill the availability requirement, a surgeon credentialed in trauma care shall be in the hospital at the time of the patient's arrival.

(c) For Level II trauma centers only, the in-hospital requirement specified in (a)3 above may be fulfilled by an anesthesiology chief resident (post-graduate year 4 or clinical anesthesia post-graduate year 4) or a certified registered nurse anesthetist (CRNA), provided that an anesthesiologist will be in the hospital at the time of the patient's arrival.

(d) For Level I and Level II trauma centers, there shall be physicians on call and promptly available in each of the following specialties:

1. Neurologic surgery;
2. Orthopedic surgery;
3. Urologic surgery;
4. Ophthalmic surgery;
5. Obstetric-gynecologic surgery;
6. Plastic surgery;
7. Oral/maxillofacial surgery;
8. Thoracic surgery;
9. Cardiology;
10. Internal medicine;
11. Pulmonary medicine;
12. Pediatrics; and
13. Radiology.

(e) For Level I trauma centers, there shall be physicians on call and promptly available in each of the following additional specialties:

1. Microvascular surgery (replant/flaps);
2. Hand surgery;
3. Cardiac surgery;

4. Pediatric surgery; and

5. Infectious disease.

8:43G-12.18 Trauma services patient services

(a) The trauma service is required to provide on-site specialized services, including, at a minimum:

1. Acute hemodialysis;

2. Radiological services as follows:

i. Angiography;

ii. Computerized tomography, with a technician present in the hospital 24 hours a day; and

iii. Nuclear scanning;

3. For Level I trauma centers, cardiac surgery designation; and

4. A critical care unit for trauma center patients with a nurse:patient ratio of at least 1:2 on each shift.

8:43G-12.19 Trauma services environment

There shall be an immediately available and adequately staffed operating room in-hospital 24 hours a day, for any emergency operative procedures needed by trauma center patients.

8:43G-12.20 Trauma services quality improvement

(a) There shall be an organized quality improvement program at Level I and Level II trauma centers that is integrated into the hospital quality assurance program and 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.

(b) The quality improvement program shall include periodic collection and review of data in at least the following areas:

1. All trauma deaths and other cases identified by clinical indicators as potential problems;

2. Morbidity review;

3. Multidisciplinary trauma conference;

4. Medical nursing audit, utilization review, tissue review;

5. Review of prehospital trauma care; and

6. Any instances of bypass or diversion of major trauma patients.

8:43G-12.21 Trauma services trauma registry

(a) Each Level I and Level II trauma center shall maintain a trauma registry enumerating demographic, injury scene, prehospital, emergency department, inpatient, and discharge/outcome data for all patients treated or evaluated by the trauma center. The trauma registry shall include all items in a minimum data set defined by the Department.

(b) All other hospitals shall maintain a trauma registry for major trauma patients, including all items in an abbreviated data set determined by the Department.

(c) In accordance with procedures which shall be established and promulgated by the Department by December 20, 2000, all hospitals shall periodically submit computerized trauma registry data to the Office of Emergency Medical Services, New Jersey Department of Health and Senior Services, for inclusion in the New Jersey State Trauma Registry.

(d) The Department shall not publicly disclose trauma registry data that identifies patients, staff, quality improvement determinations, or any data related to mortality or mortality rates for identified hospitals.

8:43G-12.22 Trauma services compliance

(a) After designation, Level I and Level II trauma centers shall demonstrate continuing compliance with the applicable requirements of this subchapter according to the following process:

1. Trauma centers shall maintain current verification at Level I or Level II in accordance with the verification review program conducted by the Committee on Trauma of the American College of Surgeons (ACS), described in Chapter 22 (page 97) of "Resources for the Optimal Care of the Injured Patient 1999," published by the Committee on Trauma, American College of Surgeons, 633 N. St. Clair Street, Chicago, IL 60611-3211, (312) 202-5456, incorporated herein by reference;

2. Trauma centers shall undergo ACS reverification reviews, at the hospital's expense, prior to expiration of current verification. The trauma center shall arrange for staff of the Office of Emergency Medical Services (OEMS) at the Department of Health and Senior Services to be present at such reviews;

3. The trauma center shall submit a copy of the written report of the ACS Verification Review Committee site visit to OEMS, and shall certify that it has corrected "criteria" deficiencies and addressed "non-criteria" recommendations contained in the ACS report within six months of receiving the report. However, individual patient chart reviews shall be considered confidential information, are not required to be submitted, and shall not be disclosed to the public;

4. The Department may use information from ACS verification reviews in the conjunction with other survey methods to determine whether licensure deficiencies have occurred, in accordance with the provisions of N.J.A.C. 8:43E; and

5. The Department may terminate the Level I or Level II designation of a trauma center for failure to maintain ACS verification or other licensure deficiencies if a continuing pattern of substandard care is demonstrated which adversely affects patient outcomes and which has not been corrected within six months. Proposed termination shall follow the process for enforcement remedies and hearings set forth in N.J.A.C. 8:43E.

8:43G-12.23 Pediatric trauma services

(a) In addition to meeting the requirements in N.J.A.C. 8:43G-12.12 through 12.22, each Level I and Level II trauma center shall continuously maintain verification by the Committee on Trauma of the American College of Surgeons (ACS) as an adult trauma center for caring for injured children, in accordance with Chapter 10 (pages 39-42) of the ACS publication identified in N.J.A.C. 8:43G-12.22(a)1, except as otherwise provided in (b) below.

(b) A Level II trauma center which cannot meet the ACS pediatric trauma requirements specified in (a) above shall enter into a transfer agreement with the Level I trauma center for its region for the triage or transfer of pediatric trauma cases which the Level II trauma center does not have the capabilities to treat.

(c) Level I and Level II trauma centers shall have licensed general pediatric beds at the same site as other trauma center facilities and resources.

SUBCHAPTER 13. HOUSEKEEPING AND LAUNDRY

8:43G-13.1 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 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 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 hospital together with their Materials Safety Data Sheet (MSDS).

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

8:43G-13.2 Housekeeping staff qualifications

There shall be a housekeeping or environmental service with a designated director who has at least two years of experience in institutional housekeeping or environmental services.

8:43G-13.3 (Reserved)

8:43G-13.4 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.

(b) All toilets and bathrooms shall be kept clean to sight and touch, in good repair, and free of odors that reflect poor housekeeping practices.

(c) Reusable hand-cleanser dispensers shall be clean inside and out. Disposable dispensers shall be discarded and not refilled.

(d) Floors shall be kept clean.

(e) Hard surfaced floors shall be coated with a slip-resistant floor finish.

(f) Carpeting shall be kept clean and odor-free and shall not be frayed, worn, torn, or buckled.

(g) Window and partitioning curtains and drapes shall be kept clean to sight and touch and odor-free.

(h) Walls, ceilings, and vents shall be kept clean to sight and touch and odor-free.

(i) Windows and screens shall be kept clean to sight and touch and in good repair.

(j) 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.

(k) All equipment and environmental surfaces shall be kept clean to sight and touch.

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

(m) Housekeeping and cleaning supplies shall be selected and approved by the Infection Control Committee. They shall be measured and used correctly and according to manufacturers' written instructions.

(n) Effective and safe controls shall be used to minimize or eliminate the presence of rodents, flies, roaches, and other vermin in the hospital. The premises shall be kept in such conditions as to prevent the breeding, harboring, or feeding of vermin. All openings to the outer air shall be effectively protected against the entrance of insects.

(o) Fly strips shall not be located over food preparation and service areas or in patient care areas.

(p) Periodic documented inspections of buildings and grounds shall be performed. Buildings and grounds shall be maintained in a clean and safe condition.

(q) 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.

(r) All communal toys shall be washed daily or more frequently as needed. No stuffed animals shall be allowed except for personal use.

(s) Plants and flowers shall not be allowed in patient treatment areas (such as operating rooms and procedure rooms) or sterile processing areas.

8:43G-13.5 Housekeeping supplies and equipment

(a) Toilet tissue and proper waste receptacles shall be provided in all toilet areas.

(b) Hand cleaner, sanitary towels, and waste receptacles or hand-drying machines shall be provided at each handwashing unit. Hand cleaner and hand-drying machines shall be approved by the infection control committee.

(c) All portable equipment, such as carts, stretchers, intravenous poles, and wheelchairs, shall be kept clean and maintained in good repair.

(d) When not in use, cleaning and disinfecting agents shall be stored on separate shelves from other supplies and in enclosed areas.

8:43G-13.6 (Reserved)

8:43G-13.7 Housekeeping staff education and training

(a) Requirements for the housekeeping education program shall be as provided in N.J.A.C. 8:43G-5.9

(b) Orientation for new housekeeping employees shall include training in cleaning and infection control techniques.

(c) For specialty units, including at least the newborn nursery, surgical suite, emergency department, pediatrics, critical care, renal dialysis, post mortem, and central services sterile preparation, housekeeping staff shall be specifically trained jointly by housekeeping and the unit staff to clean the unit to which they are assigned.

8:43G-13.8 Housekeeping quality improvement methods

(a) There shall be a program of quality improvement for housekeeping that is coordinated with the hospital quality improvement program and includes 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. 8:43G- 27, Continuous Quality Improvement.)

(b) Hospitals that contract with a commercial housekeeping service shall use quality improvement measures to ensure that the same standards are met as apply to an in-house housekeeping service.

8:43G-13.9 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, implemented, and followed, and which include at least a policy that identifies special handling practices for soiled laundry.

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

8:43G-13.10 Laundry staff qualifications

There shall be a designated director or supervisor of laundry with a minimum of two years of experience in institutional laundry service.

8:43G-13.11 Laundry patient services

(a) All laundry from patient rooms and other service areas shall be transported in such a way that no leakage occurs.

(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.

8:43G-13.12 Laundry space and environment

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

(g) If the hospital has a limited-use, home-style laundry (for example, for the use of the psychiatric unit or 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 hospital contracts with a commercial laundry service, the hospital 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 hospital 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.

8:43G-13.13 Laundry supplies and equipment

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

1. All hospitals shall provide laundered scrub suits in the following areas: surgical suites, obstetrical surgical suites, postanesthesia care unit, central services, and those areas as determined by hospital policy.

(b) If the hospital 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.

(c) The laundry service shall monitor, and retain documentation for one year, at least the following:

1. Unsafe objects found;

2. Linen supply;

3. Stained linens; 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.

8:43G-13.14 Laundry staff education and training

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

(b) Orientation for new laundry employees shall include protocols for handling and receiving soiled laundry and clean linen.

8:43G-13.15 Laundry continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the laundry service that is coordinated into the hospital continuous 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. 8:43G-27, Continuous Quality Improvement).

(b) Hospitals that contract with a commercial laundry service shall use quality improvement measures to ensure that the standards of N.J.A.C. 8:43G-13.9 through this section are met.

8:43G-13.16 Sanitation policies and procedures

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

8;43G-13.17 Sanitation staff qualifications

There shall be a designated director or supervisor of sanitation with specialized training or education in institutional sanitation service. A consultant may be used to fulfill this role.

8:43G-13.18 Sanitation patient services

(a) The water supply shall be adequate in quantity, of a safe sanitary quality, and from a water system that is constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A 58:12A-1 et seq. and N.J.A.C. 7:10 and other applicable laws, ordinances, and regulations.

1. The Safe Drinking Water Act and rules can be obtained from:

   The New Jersey Department of Environmental Protection
   Bureau of Potable Water
   P.O. Box 209
   Trenton, NJ 08625

(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.

8:43G-13.19 Sanitation space and environment

(a) Water piping carrying non-potable water shall be clearly labeled as such.

(b) The sewage disposal system shall be maintained in good repair and operated in compliance with State and local laws, ordinances, and regulations.

(c) There shall be no direct physical connections between city and well water supplies. Any physical connection between a public community water supply and an unapproved water supply, such as a well used by a hospital for emergency purposes, must be approved by the New Jersey Department of Environmental Protection and the owner of the public community water supply and must conform with N.J.A.C. 7:10-10.

(d) There shall be no back siphonage conditions present.

(e) Equipment requiring water drainage, such as ice machines, shall be drained to a sanitary connection in a way that avoids splatter or overflow.

8:43G-13.20 Sanitation quality improvement methods

The hospital shall adhere to the water sampling schedule and the chemical and biological monitoring requirements of the water supply system set by the New Jersey Department of Environmental Protection. Records of the sampling and monitoring shall be maintained.

8:43G-13.21 Regulated medical waste policies and procedures

(a) The hospital shall develop and implement and the Infection Control Program shall review, approve, and audit written policies and procedures for collection, storage, handling, transport and disposal transport of medical waste, in conformance with applicable Federal and State laws and regulations.

(b) The hospital shall comply with the provisions of 42 U.S.C. § 6903, the Medical Waste Tracking Act of 1988 and N.J.S.A 13:1E-48 et seq., the Comprehensive Regulated Medical Waste Management Act and all rules and regulations promulgated pursuant to the aforementioned Acts.

8:43G-13.22 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.

(b) Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from 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.

(c) Plastic bags shall be used for solid waste removal from patient care units and supporting 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.

(d) 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.

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

SUBCHAPTER 14. INFECTION CONTROL

8:43G-14.1 Infection control program structural organization

(a) A hospital epidemiologist shall direct and oversee the hospital Infection Control Program. A hospital epidemiologist is defined as a physician who is board certified in a medical specialty, preferably Infectious Diseases, and has training (such as a Centers for Disease Control and Prevention Course, or Society for Healthcare Epidemiology of America (SHEA) course, or a Master's Degree in Public Health) or at least five years experience in hospital epidemiology. The hospital epidemiologist may be a consultant.

(b) A hospital Infection Control Program shall be multi-disciplinary and include a hospital epidemiologist, infection control professional(s), a clinical microbiologist, and a pharmacist. In addition, the program shall have an on-going surveillance system to monitor nosocomial infections, antimicrobial resistance, antimicrobial use, and outbreaks of infectious diseases.

(c) There shall be a hospital infection control committee that includes representatives from at least: infection control, medical staff, nursing service, dietary, administration, clinical microbiology, respiratory care services, surgical services, central services, environmental services, pharmacy, and the employee health service. The chairman of the committee shall be the hospital epidemiologist. The committee shall participate in the hospital's overall quality improvement program and shall receive formal advice from all other services upon its request.

(d) The infection control program shall oversee, but not be limited to, the following activities:

1. Formulating a system for surveillance, prevention, and control of nosocomial infections.

i. Surveillance: Surveillance of nosocomial infections shall be performed. The surveillance process shall include at least the following elements:

(1) Identification and description of the problem or event to be studied;

(2) Definition of the population at risk;

(3) Selection of appropriate methods of measurements, including statistical tools and risk stratification;

(4) Identification and description of data sources and data collection personnel and methods;

(5) Definitions of numerators and denominators;

(6) Preparation and distribution of reports to appropriate groups; and

(7) Selection of specific events to be monitored and guided by validated, available benchmarks and appropriately adjusted for patient risks so that meaningful comparisons can be made.

ii. Rates are calculated from the above surveillance monitoring for

internal quality improvement activities.

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

(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 996; 24: 262-93);

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

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

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

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

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

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

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

iv. The guidelines listed in (d)1iii above are available from the National Technical Information Service (NTIS) by calling 703-487-4650 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 web site at: http://www.cdc.gov/ncidod/vancom.htm, and CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: http://www.cdc.gov/nicdod/hip/aresist/mrsahcw.htm.

2. Developing and implementing a system of infection control and isolation procedures, including Universal (OSHA)/ Standard (CDC) Precautions, using at least criteria which meet or exceed the criteria established by 29 CFR 1910.1030, OSHA's Blood Borne Pathogens regulation incorporated herein by reference, as amended and supplemented if in effect;

3. Reviewing and approving written policies and procedures for decontamination, disinfection, sterilization, and handling of regulated medical waste and all other solid waste (See N.J.A.C. 8:43G-13, Housekeeping, Laundry, and Sanitation);

4. Reviewing, every three years or more frequently as necessary, the hospital's policies and procedures related to infection control such as: isolation, aseptic technique, employee health, and staff training. Reviewing on at least an annual basis antimicrobial susceptibility and trends, the prevention of infection, and general improvement of patient care;

5. Identifying and reporting communicable diseases throughout the hospital, with the cooperation of the clinical laboratory, medical records, and the medical staff, as specified in N.J.A.C. 8:57-1 of "Communicable Diseases," also known as Chapter II of the State Sanitary Code; and

6. 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.

NOTE: Centers for Disease Control and Prevention 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

(e) The infection control program, with the cooperation of the infection control committee, shall share information, including problems, data, and relevant recommendations, with at least the quality improvement program, nursing service, administration, and the medical staff, and shall ensure that corrective actions are taken.

(f) The infection control committee shall meet at least six times per year with at least one meeting per quarter.

(g) The hospital epidemiologist and the infection control professional shall participate in the development and shall approve of all hospital policies and procedures related to infection control.

8:43G-14.2 (Reserved)

8:43G-14.3 Infection control and hospital epidemiology staff qualifications

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).

8:43G-14.4 (Reserved)

8:43G-14.5 Infection control staff time and availability.

(a) There shall be a hospital epidemiologist and infection control professional(s) who are responsible for coordination of the infection control program.

(b) There shall be a ratio of the equivalent of at least one full-time infection control professional to every 200 adjusted occupied beds, where the bed occupancy has been adjusted both for an outpatient factor and for the hospital's all-payer case mix index (CMI), using the following formula:

$$\text{Adjusted Occupied Beds} = \frac{\text{Annual Inpatient Days}}{365} \times \frac{\text{Inpatient Charges \& Outpatient Charges}}{\text{Inpatient Charges}} \times \text{All Payer CMI}$$

For every hospital, there shall be at least one half time infection control professional.

(c) Outpatient service areas provided by the hospital shall have a designated health care professional on site that is responsible for the day-to-day activities related to infection control.

8:43G-14.6 Infection control patient services

(a) Between October 1, or earlier if the vaccination is available, and February 1 of every year, provided a patient's medical condition permits, every patient aged 65 or older shall be provided the opportunity to receive vaccination against influenza, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control in effect at the time of vaccination, incorporated herein by reference. Receipt of the vaccination shall be documented on the patient's chart and made a part of the patient's permanent hospital record. Prior to administration of the vaccination, diligence shall be exercised to determine whether the patient has already received the influenza vaccination for the year in question.

1. Centers for Disease Control publications can be obtained from:

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

(b) As soon as a patient's medical condition permits, every patient aged 65 years or older shall be provided the opportunity to receive vaccination against pneumococcal disease, in accordance with the recommendations of the Advisory committee on Immunization Practices of the Centers for Disease Control in effect at the time of vaccination, incorporated herein by reference. (See CDC address in (a)1 above.) Receipt of the vaccination shall be documented on the patient's chart and made a part of the patient's permanent hospital record. Prior to administration of the vaccination, diligence shall be exercised to determine whether the patient has received the pneumococcal vaccination within the preceding 10 years.

(c) Patients refusing either or both the influenza and/or pneumococcal vaccine(s) shall be requested to sign a form indicating that the vaccine was offered, but refused. The form shall contain all relevant patient identification information. Where applicable, the form shall indicate that the vaccination was refused because the patient has already received the vaccination. In the event the patient refuses to sign the form, the form shall so indicate. The refusal shall be documented on the patient's chart and made part of the patient's permanent hospital record. The refusal form shall also become a part of the patient's permanent hospital record.

(d) Hospitals shall collect data regarding patient influenza and pneumococcal immunization and shall report that data to the Department on an annual basis, beginning July 1, 2000, for calendar year 1999 data. The data shall be limited to the number of patients aged 65 and older receiving the influenza vaccine and the number of patients aged 65 and older receiving the pneumococcal vaccine.

8:43G-14.7 Infection control staff education and training

(a) Requirements for the infection control staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) The infection control professional shall coordinate educational programs to address specific problems, as recommended by the Centers for Disease Control and Prevention, or at least annually for staff in all patient care areas and services.

(c) Orientation for all new employees shall include infection control practices related to blood and body fluid precautions (that is, personal protective equipment), isolation practices, tuberculosis education, and use of protective vaccines. Additional orientation shall be directed to the employee's specific area of service

8:43G-14.8 Infection control continuous quality improvement methods

The infection control professional shall develop and implement a program of continuous quality improvement that is integrated into the hospital continuous 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 program shall supervise these continuous quality improvement activities. These quality improvement activities shall be overseen by the continuous quality improvement program (See N.J.A.C. 8:43G-27, Continuous Quality Improvement).

8:43G-14.9 through 8:43G.14.16 (Reserved)

SUBCHAPTER 15. MEDICAL RECORDS

8:43G-15.1 Medical records structural organization

(a) There shall be a medical record department with the primary responsibility of maintaining medical records for all inpatients treated at the hospital.

(b) There shall be a system for identifying medical records to facilitate their retrieval by patient identifier.

(c) If the hospital ceases to operate, at least 14 days before cessation of operation the State Department of Health shall be notified in writing about how and where medical records will be stored.

(d) The hospital shall maintain a written organizational chart for the medical record department that delineates lines of authority and responsibility in the department.

(e) There shall be a system of access to the medical records of all patients, including outpatients.

8:43G-15.2 Medical records policies and procedures

(a) The medical record department shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. They shall include at least:

1. Procedures for record completion, including chart analysis;

2. Conditions, procedures, and fees for releasing medical information; and

3. Procedures for the protection of medical record information against the loss, tampering, alteration, destruction, or unauthorized use.

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

1. If computer generated orders with a physician's electronic signature are used, the hospital 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 Faxed to the hospital for inclusion into the medical record;

iii. The physician shall submit the original for inclusion into the medical record within 72 hours; and

iv. The faxed copy shall be replaced by the original. Facsimile reports produced by a plain-paper facsimile process can be used as an original document and do not need to be replaced by an original.

(c) Medical records, including outpatient records, shall be organized in a uniform format within each clinical service.

(d) The inpatient's complete medical record shall include at least:

1. Written informed consents, if indicated and documentation of the existence, or nonexistence, of an advance directive and the hospital's inquiry of the patient concerning this;

2. A complete history and physical examination, in accordance with medical staff policies and procedures;

3. Clinical/progress notes;

4. For surgical patients, a preanesthesia note made by the anesthesiologist before administration of anesthesia;

5. For surgical patients, an anesthesia record by the anesthesiologist or certified registered nurse anesthetist;

6. For surgical patients, a postanesthesia note made early in the postoperative period and after release from the recovery room by a member of the hospital's professional anesthesia team in accordance with policies and procedures developed in compliance with N.J.A.C. 8:43G-35.1(a);

7. For surgical patients, an operative report;

8. A postanesthesia care unit record, if applicable;

9. Consultation reports, where applicable;

10. Physician orders for treatment and medication;

11. Medication record reflecting the drug given, date, time, dosage, route of administration, and signature and status of the person administering the drug. Initials may be used after the person's full signature appears at least once on each page of the medication record. Allergies, including allergy to latex, shall be listed on the medication record;

12. A record of self-administered medications, if the patient self-administers, in accordance with the policies and procedures of the hospital's pharmacy and therapeutic committee, or its equivalent;

13. Reports of laboratory, radiological, and diagnostic services;

14. A discharge summary, which includes the reason for admission, findings, treatment, condition on discharge, medication on discharge, final diagnosis, and, in the case of death, the events leading to death and the cause of death. For cases where the patient is discharged

alive within 48 hours of admission and is not transferred to another facility, for normal newborns, and for uncomplicated deliveries, a discharge note may be substituted for the discharge summary. The discharge note includes at least the patient's condition on discharge, medications on discharge, and discharge instructions; and

15. A report of autopsy, if performed by the hospital, with provisional anatomic diagnoses recorded in the medical record within three days. The complete protocol is included in the medical record within the time specified in hospital policies and procedures.

(e) Any adverse incident, including patient injuries, shall be documented in the patient's medical record.

(f) If the patient is transferred to another health care facility (including a home health agency) on a nonemergency basis, the hospital shall maintain a transfer record reflecting the patient's immediate needs and send a copy of this record to the receiving facility at the time of transfer. The transfer record shall contain at least the following information:

1. Diagnoses, including history of any serious physical conditions unrelated to the proposed treatment which might require special attention to keep the patient safe;

2. Physician orders in effect at the time of discharge and the last time each medication was administered;

3. The patient's nursing needs;

4. Hazardous behavioral problems;

5. Drug and other allergies; and

6. A copy of the patient's advance directive, where available.

(g) Medical records shall be completed within 30 days of discharge.

(h) Medical records shall be retained and preserved in accordance with N.J.S.A. 26:8-5 et seq.

(i) Original medical records of components of medical records shall not leave hospital premises unless they are under court order or subpoena or in order to safeguard the record in case of a physical plant emergency or natural disaster.

(j) Any consent form for medical treatment that the patient signs shall be printed in an understandable format and the text written in clear, legible, nontechnical language. In the case where someone other than the patient signs the forms, the reason for the patient's not signing it shall be indicated on the face of the form, along with the relationship of the signer to the patient.

(k) The patient's death shall be documented in the patient's medical record upon death.

(l) Recording errors in the medical record shall be corrected by drawing a single line through the incorrect entry. The date of correction and legible signature or initials of the person correcting the error shall be included.

(m) All medical records, including outpatient medical records, shall be organized in a uniform format within each clinical service.

8:43G-15.3 Medical record patient services

(a) Health care practitioners who provide clinical services to the patient shall enter clinical/progress notes in the patient's medical record, when the services are rendered.

(b) Notes that provide a full and accurate description of the care provided to the patient shall be made in the medical record at the time clinical services are provided. Notes that provide a description and an evaluation of the patient's response to treatment shall be made in the medical record.

(c) The medical record shall either accompany the patient when he or she leaves the patient care unit for clinical services in other departments of the hospital or shall be retrievable by authorized personnel on a computerized system with a restricted access and entry system.

(d) If a patient or the patient's legally authorized representative requests, in writing, a copy of his or her medical record, a legible, written copy of the record shall be furnished at a fee based on actual costs. One copy of the medical record from an individual admission shall be provided to the patient or the patient's legally authorized representative 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. (Although the patient may have had more than one admission, and thus more than one record is provided, only one search fee shall be permitted for that request. The search fee is permitted even though no medical record is found as a result of the search.); and

ii. A postage charge of actual costs for mailing. No charges shall be assessed other than those permitted in (d)1 and 2 above;

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

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

5. For purposes of this subsection, "legally authorized representative" means the following:

i. Spouse;

ii. Immediate next of kin;

iii. Legal guardian;

iv. Patient's attorney;

v. Patient's third party insurer; and

vi. Worker's compensation carriers, where access is permitted by contract or law, but limited only to that portion of the medical record which is relevant to the specific work-related incident at issue in the worker's compensation claim.

(e) The fee for copying medical records shall be based on actual costs, which in no case shall exceed $1.00 per page and $10.00 per search, in the case of the following:

1. Where the patient has authorized release of his or her medical record to a person or entity other than those identified in (d) above, including but not limited to physicians or other practitioners who provided care to the patient, or attorneys representing such providers; or

2. The patient subsequently requests additional copies of a medical record which has been furnished in accordance with (d) above.

(f) Access 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.

(g) The patient shall have the right to attach a brief comment or statement to his or her medical record after completion of the medical record.

8:43G-15.4 Medical records staff qualifications

There shall be a full-time medical record director who is an accredited record technician or a registered record administrator under a certification program approved by the American Medical Record Association.

8:43G-15.5 Staff education

Requirements for the medical record staff education and training program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-15.6 (Reserved)

8:43G-15.7 Medical record continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for medical records that is integrated into the hospital continuous quality improvement program and 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.

(b) Continuous quality improvement activities for the medical record department shall include monitoring medical records for accuracy, completeness, legibility, and accessibility.

SUBCHAPTER 16. MEDICAL STAFF

8:43G-16.1 Medical staff structural organization

(a) There shall be an organized medical staff that is responsible to the governing body of the hospital. Bylaws governing all medical staff members shall be implemented.

(b) Applications for membership, privileges, or initial appointment to the medical staff shall be processed under a system that includes, at least, the verification of applicants' credentials, periodic review of privileges, and obtaining information about any disciplinary action against the applicant available from the New Jersey Board of Medical Examiners or the Federal Clearinghouse established pursuant to the Health Care Quality Improvement Act, P.L. 99-660; 100 STAT 3743.

(c) Applications for medical staff membership, clinical privileges, or initial appointment submitted by health professionals who are not practitioners, shall be reviewed according to the same established criteria and procedures that govern physicians' applications, including obtaining information about any disciplinary action by New Jersey professional licensing boards.

(d) A committee or mechanism shall be established to be responsible for examining applications for appointment and reappointment to all categories of the medical staff. This committee shall recommend the conferring or withholding of all staff positions. It shall assure that all credentials are documented and verified.

(e) Medical staff privileges shall be specifically delineated and based on the practitioner's training, experience and demonstrations of clinical competence.

(f) The medical staff shall be divided into clinical departments. Each department shall be directed by a director, physician director, chairman or chief who is responsible for its administration and for taking or recommending action in those instances in which staff members fail to meet the department's standards of quality of care.

(g) There shall be an executive committee for the medical staff which performs supervisory functions, including reviewing patient care policies and procedures and serving as a forum for discussing patient care issues identified by the clinical departments.

(h) A medical staff meeting shall be held at least annually for all active staff members.

(i) The hospital and medical staff shall have a formal program addressing impaired practitioners. This program shall include the following components:

i. Policies and a mechanism which encourage the voluntary or informal identification or reporting of practitioner impairment to the hospital;

ii. A mechanism for monitoring physician performance and for the limitation of clinical privileges if appropriate; and

iii. A procedure for the referral of impaired practitioners to appropriate treatment.

(j) The clinical privileges of all individuals shall be fully reviewed periodically. Actions which result in reduction or restriction of staff privileges based on this review shall be reported to the New Jersey Board of Medical Examiners in accordance with N.J.S.A. 26:2H-12.2.

(k) The hospital shall notify the New Jersey State Board of Medical Examiners, or a medical practitioner review panel created by legislation and subordinate to the Board, if a practitioner who is employed by, under contract to render professional services to, or has privileges at the hospital:

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

2. Voluntarily relinquishes any partial privileges to perform a specific procedure while the hospital is reviewing the practitioner's conduct or patient care or has, through any member of the medical or administrative staff, expressed 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, non-routine concurrent or retrospective review of admissions or care, non-routine 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 he or she may not exercise clinical privileges or practice within the hospital if the reasons provided in support of the leave relate to any physical, mental, or emotional condition or drug or alcohol use, which might impair the practitioner's ability to practice with reasonable skill and safety;

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

7. Has privileges, conditions or limitations reinstated or a leave of absence concluded where the results of the investigation clear the practitioner from all allegations of misconduct, impairment, or incompetence.

(l) Notifications required by (k) above shall be provided within seven days of the reported event and shall be submitted on forms approved by the Department of Health for that purpose.

(m) The hospital shall provide upon request to the State Board of Medical Examiners, or to a practitioner review panel created by legislation and reporting to the board, such additional information on individual instances of loss or change of physician privileges, possible impairments, and medical malpractice liability as the board or panel requests in accordance with law.

(n) The hospital shall provide to the following:

Office of the Assistant Commissioner

Division of Health Facilities Evaluation
New Jersey State Department of Health
PO Box 367
Trenton, N.J. 08625-0367

copies of all reports regarding physician hospital privileges sent to the New Jersey State Board of Medical Examiners, or to the practitioner review panel created by legislation and reporting to the board. All records regarding such copies shall be made available to the Department of Health personnel for official purposes and, for each report, to the specific facility mentioned in the report.

(o) For the purposes of (k) through (n) above, "practitioner" means only a person licensed to practice: medicine and surgery under N.J.S.A. 45:9-1 et seq. or a medical resident or intern; or podiatry under N.J.S.A. 45:5-1 et seq.

8:43G-16.2 Medical staff policies and procedures

(a) The medical staff shall have written policies, procedures, and bylaws that are reviewed at least once every three years; revised more frequently as needed, and implemented. They shall include at least:

1. Policies and procedures addressing the requirements for obtaining written informed consent from patients;

2. Requirements for the completeness and timing of the patient history and physical examination, including a listing of the minimum contents to be included in the medical record;

3. The minimum content of physician orders;

4. 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;

5. If applicable, policies and procedures related to the prescribing or ordering of medications or devices by certified nurse practitioners/clinical nurse specialists in accordance with New Jersey State Board of Nursing rules at N.J.A.C. 13:37-7; and

6. If applicable, the scope of practice, supervision, and record keeping requirements of licensed physician assistants in accordance with New Jersey State Board of Medical Examiners rules at N.J.A.C. 13:35-2B.

(b) All physician orders for medication, treatment, and restraints shall be in writing. All orders for restraints shall be made in accordance with requirements at N.J.A.C. 8:43G-18.4(c) through (e) and (i).

(c) The medical staff shall have a means to assess individual patient's competence to consent to treatment in conformance with current law. Measurement of patient competence may include such skills as ability to understand their medical condition and the consequences of procedures and treatments, and to communicate a choice. The hospital and physician shall follow the procedures for appointment of a special medical guardian where required in accordance with the Civil Practice Rules at 4:83-12.

(d) Each time the attending physician visits the patient, the physician shall enter a note into the medical record describing the findings about the patient's condition. If issues have been raised in the record by other disciplines, this note shall respond to them.

(e) The hospital shall comply with the New Jersey State Board of Medical Examiners rules concerning the registration and permit requirements for graduate medical education programs and practice, N.J.A.C. 13:35-1.5.

(f) The hospital shall require that all prescriptions and orders issued by registered first-year residents in the inpatient setting be countersigned by a licensed physician or permit holder (a person authorized in the State of New Jersey to engage in the practice of medicine in the second year of a graduate medical education program or beyond).

8:43G-16.3 Medical staff qualifications

(a) All physicians with clinical privileges shall be licensed or authorized to practice medicine by the New Jersey Board of Medical Examiners. All non-physicians with privileges shall be licensed or authorized to practice in the State of New Jersey, as required by law.

(b) In any subchapter of these rules requiring a practitioner to be Board-certified within his or her medical specialty, it shall be deemed acceptable to possess:

i. Board certification from one of the recognized boards of osteopathic medicine; or

ii. 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.

8:43G-16.4 (Reserved)

8:43G-16.5 Medical staff time and availability

(a) The hospital shall establish policies and procedures for response times for emergencies.

(b) There shall be an on-call list of medical and surgical specialists that is available to personnel in all patient care units.

8:43G-16.6 Medical staff patient services

(a) Each patient shall have an attending physician who has overall responsibility for the patient's care in the hospital.

(b) Each patient admitted to the hospital shall have a medical history and physical examination that includes a provisional diagnosis performed by a clinical practitioner within seven days prior to admission or within 24 hours after admission. If the history and physical were performed within seven days prior to admission, the patient's history and physical examination record completed by the attending physician, advanced practice nurse or physician assistant shall be included in the medical record, with any subsequent changes recorded at the time of admission.

(c) When there is a clinical consultant, he or she shall issue a report that states at least the assessment mechanisms used, findings, and opinion. This report shall be included in the medical record.

(d) The reason or reasons for requesting a clinical consultation shall be specified in the patient's medical record by the attending physician. The consultant shall provide consultation in accordance with the privileges accorded him or her by the hospital.

(e) Medical care shall be provided to all patients, regardless of their ability to pay.

(f) Every acute care patient shall receive a visit by a clinical practitioner every day unless there is a clinical basis to justify the patient not receiving such a visit that is documented in the medical record by the practitioner. In all cases a patient shall receive a visit by a practitioner at least once every two days.

8:43G-16.7 Medical staff education

Requirements for the medical staff education program shall be as provided in N.J.A.C. 8:43G-5.9(a) and (b).

8:43G-16.8 Medical staff continuous quality improvement methods

There shall be a medical staff mechanism by which the quality of medical care is monitored, problems identified, solutions recommended and implemented, and follow-up conducted. Summary reports of these activities and problems in the quality of care shall be reviewed by the medical executive committee, or its equivalent.

SUBCHAPTER 17. NURSE STAFFING

8:43G-17.1 Nurse staffing

(a) The hospital shall have in place a staffing plan that addresses nurse staffing requirements and identifies patient needs, including, at a minimum:

1. A daily staffing schedule that ensures at least one registered professional nurse in charge and assigned exclusively to each patient care unit on each shift;

2. A provision that at least 65 percent of direct patient care hours in inpatient units on a hospital wide average be provided by licensed nursing personnel;

3. A method for assessing each unit's additional nursing needs for each shift, including, at a minimum, objective criteria such as:

i. Documented skills, training and competency of staff to plan and provide nursing services in the nursing areas where they function;

ii. Patient data base incorporating objective factors such as case mix index, specific or aggregate patient diagnostic classifications or acuity levels, patient profiles, critical pathways or careprogression plans, length of stay, and discharge plans;

iii. Operational factors such as unit size, design, and capacity, admission/discharge/transfer index, and support service availability;

iv. Contingency plans to address critical departures from staffing plan, including policies and procedures to regulate closure of available beds if staffing levels fall below specified levels;

v. Policies and procedures for the reassignment of staff including float and agency staff; and

4. On-going internal institutional evaluation of outcome-based quality indicators related to nursing care to assess and provide a safe and adequate level of patient care including at least:

i. Patient injury rate;

ii. Medication process errors;

iii. Maintenance of skin integrity;

iv. Nosocomial infection rates;

v. Hospital-wide patient satisfaction with overall care, including nursing care;

vi. Nursing turnover rate;

vii. Patient satisfaction with pain management; and

viii. Mix of RNs, LPNs and unlicensed staff caring for patients.

(b) There shall be a registered nurse manager for each patient care unit or units and for surgery, emergency department, and other units, as specified in the hospital organizational plan or policies and procedures.

(c) There shall be at least one registered professional nurse in charge and assigned exclusively to each patient care unit on each shift. Additional staff shall be assigned by the hospital as required by the acuity levels.

(d) Patient care assignments shall be made on an individual basis by a registered professional nurse and reflect staff competence, skill, and aptitude and patient needs.

(e) The hospital shall have in effect a contingency plan for assuring adequate nurse staffing at all times. The plan shall detail policies and procedures to regulate closure of available beds, if actual staffing levels fall below specified levels.

(f) Nurse staffing for all patient care units within the hospital shall also be in accordance with:

1. N.J.A.C. 8:43G-7.5(a), (b) and (c) in accordance with N.J.A.C. 8:43G-9.20(a)6 and (i);
2. N.J.A.C. 8:43G-7.15(d);
3. N.J.A.C. 8:43G-7.16(a)2 and 3i;
4. N.J.A.C. 8:43G-7.24(a)2 and 3i;
5. N.J.A.C. 8:43G-7.27(a)2 and 3i;
6. N.J.A.C. 8:43G-9.4(a)11;
7. N.J.A.C. 8:43G-9.5(c), (d) and (e);
8. N.J.A.C. 8:43G-9.5(c), (d) and (e);
9. N.J.A.C. 8:43G-9.7(a) and (b);
10. N.J.A.C. 8:43G-9.7(a) and (b);
11. N.J.A.C. 8:43G-9.7(a);
12. N.J.A.C. 8:43G-9.14;
13. N.J.A.C. 8:43G-9.20(a)6 and (c);
14. N.J.A.C. 8:43G-9.23;

15. N.J.A.C. 8:43G-11.4(a) and (b);

16. N.J.A.C. 8:43G-12.3(e), and (g)1 through 4;

17. N.J.A.C. 8:43G-12.5(e);

18. N.J.A.C. 8:43G-12.7(a);

19. N.J.A.C. 8:43G-12.16(c) and (d);

20. N.J.A.C. 8:43G-14.1(a);

21. N.J.A.C. 8:43G-16.6(a), (b) and (f);

22. N.J.A.C. 8:43G-19.1(b) and (f);

23. N.J.A.C. 8:43G-19.3(b)1 through 3 and (c);

24. N.J.A.C. 8:43G-19.3(d);

25. N.J.A.C. 8:43G-19.11(a);

26. N.J.A.C. 8:43G-19.13(a) and (c);

27. N.J.A.C. 8:43G-19.15(b);

28. N.J.A.C. 8:43G-19.16(c), (f) and (g);

29. N.J.A.C. 8:43G-19.17(c) and (f);

30. N.J.A.C. 8:43G-19.18(d) and (h);

31. N.J.A.C. 8:43G-19.24;

32. N.J.A.C. 8:43G-19.25;

33. N.J.A.C. 8:43G-20.1(a)1;

34. N.J.A.C. 8:43G-20.2(a);

35. N.J.A.C. 8:43G-21.5(a) and (b);

36. N.J.A.C. 8:43G-22.10(b);

37. N.J.A.C. 8:43G-22.15(f);

38. N.J.A.C. 8:43G-22.16(b);

39. N.J.A.C. 8:43G-26.3(c);

40. N.J.A.C. 8:43G-26.5(b); and

41. N.J.A.C. 8:43G-27(d)4.

8:43G-17.2 (Reserved)

SUBCHAPTER 18. NURSING CARE

8:43G-18.1 Nursing care structural organization

(a) A written organizational chart and written plan that delineates lines of authority, accountability, and communication shall be available to all nursing personnel in the hospital at all times.

(b) At all times a registered professional nurse with supervisory responsibility shall be designated and authorized to act in the absence of the chief nursing executive.

8:43G-18.2 Nursing care policies and procedures

(a) The hospital shall have written policies and procedures for the nursing care service that guide nursing practices in the hospital. These policies shall be reviewed at least once every three years, revised more frequently as needed, and implemented. These policies and procedures shall conform with the Nurse Practice Act, N.J.S.A. 45:11-23 and N.J.A.C. 13:37-1.4, 6.1, 6.2, 13.1 and 13.2.

(b) The hospital's current clinical and administrative nursing policies and procedures shall be available to all nursing personnel on each patient care unit at all times.

8:43G-18.3 Nursing care staff qualifications

(a) The nursing care service shall be directed on a full-time basis by a chief nursing executive who has at least one of the following qualifications:

1. Is a registered professional nurse with a baccalaureate degree from an accredited college or university, and five years combined clinical and progressive management experience in nursing;

2. Is a registered professional nurse with a baccalaureate degree in nursing science and three years combined clinical and progressive management experience in nursing; or

3. Is a registered professional nurse with a baccalaureate degree from an accredited college or university and a master's degree in nursing or a health related field from an accredited college or university and three years combined clinical and progressive management experience in nursing.

(b) Any individual holding the title of chief nursing executive upon the effective date of these rules shall be exempt from the qualifications in (a) above.

(c) Before newly hired nurses provide patient care services, the hospital shall verify licensure or permission to work letters by visually examining the current pocket license or original permission to work letter.

(d) Before newly hired nurses provide patient care services, they shall receive orientation that takes into account each individual's competency and skills and includes at least:

1. The policies and procedures of the nursing service;

2. How to find a written copy of the policies and procedures of the service to which he or she will be assigned;

3. Available resources; and

4. Channels of communication, emergency and otherwise.

(e) The hospital shall develop and implement a criteria-based system for evaluating at least annually the performance of each nursing service employee.

(f) The hospital, under the direction of the nursing service, shall utilize the approved State Board of Nursing Unlicensed Assistive Personnel (UAP) curriculum, incorporated herein by reference, as amended and supplemented, in the development and implementation of a training program for unlicensed assistive personnel. There shall be methods for evaluating minimal competencies and a requirement for annual in-service education. A copy of the State Board of Nursing UAP curriculum may be obtained by sending a request to the following address:

Executive Director
State Board of Nursing
124 Halsey Street
Newark, New Jersey 07102

(g) The hospital, under the direction of the nursing service, shall develop and implement a training program for unlicensed assistive personnel including training and demonstrations in basic nursing tasks and incorporating the principles of patient rights, infection control, and safety. There shall be methods for evaluating minimal competencies and a requirement for annual in-service education.

(h) The hospital shall have a system for evaluating all supplemental nursing staff, including agency and hospital registry nurses, and excluding from use those who do not receive favorable evaluations.

(i) There shall be a system for defining and evaluating the practices of private duty nursing personnel.

8:43G-18.4 Nursing care; use of restraints

(a) The standards in this section shall apply to the use of physical restraints in all patient care areas of the hospital. Physical restraints are defined as devices, materials, or equipment that are attached or adjacent to a person and that prevent free bodily movement to a position of choice, with the exception of devices used for positioning supports necessary for medical treatment.

(b) The hospital shall have written policies and procedures regarding the use of physical restraints that are reviewed at least once every three years, revised more frequently as needed, and implemented. They shall include at least the following:

1. Protocol for the use of alternatives to physical restraints, such as staff or environmental interventions, structured activities, or behavior management. Alternatives shall be utilized whenever possible to avoid the use of restraints;

2. Protocol for the use and documentation of a progressive range of restraining procedures from the least restrictive to the most restrictive;

3. A delineation of indications for use, which shall be limited to:

i. Prevention of imminent harm to the patient or other persons when other means of control are not effective or appropriate; or

ii. Prevention of serious disruption of treatment or significant damage to the physical environment;

4. Contraindications for use, including at least clinical contraindications, convenience of staff, or discipline of the patient;

5. Identification of restraints which may be used in the hospital, which shall be limited to methods and mechanical devices that are specifically manufactured for the purpose of physical restraint;

6. Protocols for notifying the family or guardian of reasons for use of restraints, and for informing the patient and requesting consent when clinically feasible; and

7. Protocol for removal of restraints when goals have been accomplished.

(c) Except in an emergency, a patient shall be physically restrained only after the attending physician or another designated physician has personally seen and evaluated the patient and has executed a written order for restraint.

(d) An emergency restraint procedure, beginning with the least restrictive alternative that is clinically feasible, shall be initiated by a registered professional nurse only when the safety of the patient or others is endangered or there is imminent risk that the patient will cause substantial property damage. The attending physician, another designated physician, a licensed physician assistant, or a nurse practitioner/clinical nurse specialist shall be notified immediately and shall respond within one hour. An order shall be given if the use of restraints is to continue beyond one hour. The clinical condition of the patient shall be evaluated and documented by medical or licensed nursing personnel at least once every two hours.

(e) In all cases, the attending or designated physician, licensed physician assistant, or advanced practice nurse shall observe the restrained patient at least once every 24 hours to evaluate any changes in the patient's clinical status. This evaluation shall be documented in the patient record. If a physician has ordered the use of restraints, a subsequent order for the use of restraints shall not be required so long as its use is in compliance with the intent of the original order and hospital policy.

(f) Interventions while a patient is restrained, except as indicated at (g) below, shall be performed by nursing personnel in accordance with nursing care policy. They shall include at least the following and shall be documented:

1. Assessment for clinical status and reevaluation of need for restraints at least every two hours;

2. Toileting at least every two hours with assistance if needed;

3. Monitoring of vital signs; and

4. Release of restraints at least once every two hours in order to:

i. Assess circulation and skin integrity;

ii. Perform skin care; and

iii. Provide an opportunity for exercise or perform range of motion procedures for a minimum of five minutes per limb.

5. Continuous or periodic visual observation based upon an evaluation of the patient's clinical condition.

6. Administration and monitoring of adequate fluid intake;

7. Adequate nutrition through meals at regular intervals, snacks, and assistance with feeding if needed;

8. Assistance with bathing as required, occurring at least once a day; and

9. Ambulation at least once every four hours if clinically feasible.

(g) Interventions for patients wearing vest or similar restraints for overnight sleeping shall be performed by nursing personnel in accordance with nursing care policy. They shall include at least the following and shall be documented:

1. Periodic visual observation based on patient acuity occurring at least once every hour;

2. Administration of fluids as required;

3. Toileting as required; and

4. Release of restraints at least once every two hours for repositioning and skin care, unless clinically contraindicated.

(h) Registered professional nursing staff shall evaluate and ensure appropriate monitoring and documentation of the effects of all psychotropic medications. These medications shall be administered only upon written physician orders as part of the patient's treatment plan and shall not be used as a method of restraint, discipline, or for the convenience of staff.

8:43G-18.5 Nursing care patient services

(a) Registered professional nurses and licensed practical nurses shall provide patient care commensurate with their scope of practice, as delineated in the Nurse Practice Act.

1. Patient care may be provided by certified nurse practitioners/clinical nurse specialists in accordance with New Jersey State Board of Nursing rules at N.J.A.C. 13:37-7.

2. Nursing students shall render care to patients only when qualified supervision, as defined by the hospital and the nursing school, is available in the unit.

(b) All patients shall be under the supervised care of a registered professional nurse at all times.

(c) The nursing plan of care shall be consistent with the medical plan of care and implemented in accordance with the Nurse Practice Act.

(d) A registered professional nurse shall perform an initial assessment of the patient and identify patient problems for each patient upon admission. A completed assessment note, which addresses patient problems, identifies expected patient outcomes, and includes anticipated discharge needs, shall be prepared by a registered professional nurse within 24 hours of admission. The patient's anticipated discharge requirements shall be communicated as needed to the professional responsible for discharge planning or case coordination in accordance with facility policy.

(e) Each patient shall receive nursing care that is organized around ongoing, patient-specific care planning and is consistent with medical care planning. The planning shall include setting measurable goals with the patient and family to the extent possible. This planning, nursing interventions, and patient responses shall be documented in the medical record as defined by hospital policy.

(f) The patient's or family's educational needs shall be met throughout the hospital stay, unless they are not capable of receiving education, and shall include at least:

1. Orientation to the patient's environment;

2. How and when to communicate with the staff;

3. Information about the patient's medications and their administration;

4. The patient's activity limitations and professional expectations of his or her activity level;

5. The patient diet; and

6. Information about the extent of self-care that can be rendered during the hospital stay and after discharge.

(g) There shall be a system for receiving, evaluating, and addressing patient and family concerns related to nursing care.

(h) All nursing staff shall wear easily readable name tags that include their name and status, such as RN, LPN, unit clerk, or nurse assistant. The hospital shall have a policy to identify nursing unit exceptions to this procedure where necessary.

(i) Patient discharge instructions shall be documented in the patient's medical record at the time of discharge.

(j) Allergies shall be listed on the front cover of the patient's chart or, in a computerized system, highlighted on the screen.

(k) Patients who require assistance in feeding shall be identified, and there shall be a mechanism in place to assure that assistance is provided.

8:43G-18.6 Nursing care services related to pharmaceutical services

(a) All medications administered by nursing personnel shall be administered in accordance with prescriber orders, medical staff policy, and all Federal and State laws and regulations.

(b) Medications for individual patients shall not be removed from their original prescription containers by nursing personnel until the time of drug administration.

(c) Drugs packaged in unit dose containers shall not be removed from the containers by nursing personnel until the time of drug administration. Such drugs shall be administered immediately after the dose has been removed from the container, and by the individual who prepared the dose for 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) If the facility permits self-administration of drugs, nursing personnel shall implement policies and procedures approved by the pharmacy and therapeutics committee regarding self-administration of drugs.

(g) Nursing personnel shall report drug errors and adverse drug reactions immediately to the nurse in charge of the unit and to the prescriber. By the end of the shift, an entry shall be made in the patient's medical record. The incident shall be reported in accordance with policies and procedures concerning quality assurance and risk management. The incident shall be reported to the pharmacy, in accordance with policies and procedures approved by the pharmacy and therapeutics committee, within 24 hours.

(h) Drugs in patient care areas shall be maintained under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.

(i) All drugs, needles, and syringes in patient care areas shall be kept in locked storage areas, except those drugs exempted by the pharmacy and therapeutics committee or equivalent under specified conditions. Drugs for external use shall be kept separate from drugs for internal use.

(j) Nursing personnel shall return drugs to the pharmacy for disposal in accordance with N.J.A.C. 8:43G-23.6(i).

(k) Nursing personnel shall store, use, and dispose of needles and syringes in accordance with all applicable Federal and State laws and rules, including those specified at N.J.A.C. 8:43G-14.12(b).

8:43G-18.7 Nursing care staff education and training

(a) Requirements for the nursing care education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) All nursing staff shall receive orientation and annual training regarding the use of restraints, including at least:

1. Policies and procedures in accordance with N.J.A.C. 8:43G-18.4(a);

2. Emergency and nonemergency procedures; and

3. Interventions by licensed and non-licensed nursing personnel.

8:43G-18.8 (Reserved)

8:43G-18.9 Nursing care continuous quality improvement methods

There shall be a program of continuous quality improvement for nursing care that is integrated into the hospital continuous quality improvement program and 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. Issues shall be identified through, at least, incident reports, infection control activities, and patient and staff comment.

SUBCHAPTER 19. OBSTETRICS

8:43G-19.1 Scope of obstetrical standards--definitions; structural organization

(a) The standards in this subchapter shall apply only to hospitals that have a separate, designated unit or service for obstetrics.

(b) The following terms, when used in this subchapter, shall have the following meanings:

"Advanced practice nurse" means a licensed registered professional nurse with certification in a specialty requiring expertise in maternal and child health who has been certified by the New Jersey Board of Nursing as specified in N.J.A.C. 13:37-7.

"Birth center" means an ambulatory care facility or a distinct part of a facility which is separately licensed as an ambulatory care facility and provides routine prenatal and intrapartal care. These facilities provide care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth.

"Community Perinatal Center" (CPC) means a licensed hospital designated within a Maternal and Child Health Service Region as one of the following:

1. "Basic" provides care to uncomplicated maternity patients and neonates in accordance with the scope of functions delineated in its formal letter of agreement with the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 2,499 grams and at least 36 weeks gestation.

2. "Intermediate" provides care to complicated maternity patients and neonates in accordance with the scope of functions delineated in its letter of agreement with the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 1,499 grams and at least 32 weeks gestation.

3. "Intensive" provides care to complicated maternity patients and neonates in accordance with the scope of functions delineated in its letter of agreement with the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 999 grams and at least 28 weeks gestation.

"Contact hour" means a unit of measurement that describes 50 minutes of an approved, organized learning experience, either didactic or clinical practice.

"Letter of agreement" means the document which defines the relationship between a Regional Perinatal Center and a Community Perinatal Center and specifies all tasks to be provided. This document must be developed in cooperation with the Maternal and Child Health Consortia in the region and signed by both facilities.

"Member in good standing" means that an acute care hospital has made timely payment of Maternal and Child Health Consortium (MCHC) financial assessments in accordance with the MCHC by-laws, which are based on a budget approved by the Department of Health and Senior Services.

"Obstetric patient" means a female patient at any stage of pregnancy, including antepartum, and up to six weeks post partum, whose primary diagnosis is related to the management of labor, pregnancy complications or complications of the puperium.

"Risk reduction specialist" means a registered professional nurse, a licensed or certified social worker or other professional in a maternal and child health addiction related field, who has specialized training and experience in perinatal addiction.

(c) All hospitals with obstetric services shall satisfy the following conditions:

1. The hospital shall be designated as a Community Perinatal Center or a Regional Perinatal Center; and

2. The hospital shall be a member in good standing of a Maternal and Child Health Consortium.

(d) All hospitals shall provide services in accordance with a letter of agreement facilitated by the Maternal Child Health Consortium for its region. Such services shall include:

1. Prenatal and pediatric services in accordance with the HealthStart Standards, N.J.A.C. 10:49-3; and

2. Routine prenatal care which incorporates use of a comprehensive standardized perinatal record.

(e) All Community Perinatal Centers shall have a written protocol which addresses the management of patients assessed to be at risk during the prenatal period. This protocol shall assure referral of the patient to a provider with advanced capabilities in maternal-fetal medicine for initial consultation and, if appropriate, treatment.

(f) All Regional Perinatal Centers shall have a distinct prenatal clinic service devoted to women identified as high risk. This clinic shall be staffed by an advanced practice nurse on-site and a risk reduction specialist available during hours of operation. One individual may fill both positions.

(g) All Regional Perinatal Centers shall provide high risk infant follow-up service accordance with N.J.A.C. 8:33C.

8:43G-19.2 Obstetrics policies and procedures

(a) The obstetric 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 be available in all areas of the obstetric service and include at least:

1. Criteria for the identification of high-risk obstetric and newborn patients;

2. Guidelines for when to call a physician during labor;

3. Qualifications for nurses who provide maternal and infant care appropriate to the level of care provided;

4. The use of fetal monitors;

5. A protocol for the use of oxytoxics for induction and stimulation of labor, including physician assessment of the patient before the drug's use, monitoring of the patient and fetus during its use, indications for discontinuance of the drug, educating staff in the use of oxytocin and a policy which addresses the availability of a physician to manage any complications that may arise during infusion;

6. A system for identifying hospital personnel while they are working in the unit;

7. The attire required to be worn in the labor and delivery areas;

8. A visitors policy that includes who may visit the unit and at what times, security procedures for monitoring and controlling visitors, and infection control instructions;

9. Guidelines for rooming in, if applicable; and

10. A system to provide written and oral discharge instructions from professional staff to patients upon discharge.

(b) A current list of physicians and nurse-midwives, their specific obstetric service privileges, and an on-call schedule shall be available in the department to professional staff.

(c) On obstetric units where Cesarean sections are performed, all requirements of surgical standards shall apply.

(d) The hospital shall require submission of a copy of the prenatal record for all patients registered to deliver at the hospital once the patient reaches 34 weeks gestation. These prenatal records shall be accessible to the obstetrical unit at all times.

(e) Restrictions shall be established and posted governing entry into the delivery/cesarean suite.

(f) Entry into the surgical area shall be restricted to staff and support persons. Scrub attire shall be required.

(g) All pregnant women admitted to the hospital with unknown or undocumented hepatitis-B surface antigen (HBsAg) assay results shall be immediately screened for the hepatitis-B virus using the HBsAg test or other standardized hepatitis-B tests. Test results should be available within 24 hours but no later than 48 hours. All positive HBsAg test results shall be reported on a designated reporting form within five working days of determination to the New Jersey Department of Health and Senior Services, Immunization Program.

8:43G-19.3 Obstetrics staff qualifications

(a) There shall be a physician director of the obstetric service who is responsible for all obstetric care in the hospital and is board certified in obstetrics.

(b) There shall be a nurse manager of the obstetric service, which may include labor and delivery, who is a registered professional nurse and who has:

1. A minimum of three years of experience in inpatient obstetric services within the five years immediately preceding the date of appointment;

2. Educational preparation in maternal-fetal neonatal nursing, in accordance with hospital policy; and

3. Completion of 24 contact hours in maternal-fetal or neonatal nursing approved by a nationally recognized nurse education accrediting body every three years.

(c) All health professionals assigned to the post-partum service shall be trained in the care of both mothers and infants.

(d) Hospitals designated as a CPC-Intensive or Regional Perinatal Center shall have an advanced practice nurse who is responsible for in-house and regional staff training and consultation in perinatal care. This individual shall be a registered professional nurse with a master's degree in a maternal and child health nursing specialty from an accredited college or university and who has:

1. A minimum of three years experience in maternal and child health inpatient services within the five years immediately preceding the date of appointment; and

2. Certification by the National Certification Corporation for the Obstetric, Gynecologic, and Neonatal Nursing Specialties or American Nurses' Association.

8:43G-19.4 Obstetrics staff time and availability

(a) The obstetric service in hospitals designated as a CPC-Basic shall be covered at all times by a board eligible or certified obstetrician or a board eligible or certified family practice physician with obstetric privileges, who is present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions. If coverage is provided by a family practice physician as described above, there shall be a mechanism of coverage to ensure that an obstetrician is able to arrive within 30 minutes of being summoned to perform a cesarean section.

(b) The obstetric service in hospitals designated as a CPC-Intermediate shall be covered at all times by a board eligible or certified obstetrician or board eligible or certified family practice physician with obstetric privileges, or an obstetric resident with at least three years of training, who is either present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions. If coverage is provided by a family practice physician as described above, there shall be a mechanism of coverage to ensure that an obstetrician is able to arrive within 30 minutes of being summoned to perform a cesarean section.

(c) The obstetric service in hospitals designated as Community Perinatal Centers Intensive shall be covered at all times by a board eligible or certified obstetrician, who is present in the hospital.

(d) The obstetric service in hospitals designated as a Regional Perinatal Center shall be covered at all times by a board certified obstetrician with certification in maternal-fetal medicine, who is either present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions. This physician may fulfill the requirement for physician coverage at (c) above during those times in which he or she is present in the hospital.

8:43G-19.5 Obstetrics patient services

(a) Obstetric patients shall be informed upon admission about hospital policies and procedures, including at least policies regarding visitors, and the unit's security procedures.

(b) Prenatal instruction shall be offered and include, at a minimum, information about childbirth, parenting, breast and breast/bottle feeding, immunizations, prevention of infection and disease in infants, and alternative methods of pain management during childbirth.

(c) There shall be the capability of starting a Cesarean section within 30 minutes of the decision to perform such a delivery method.

(d) The medical record for the obstetric patient shall include the prenatal record, documentation of the course of labor, including fetal monitoring strip or any other comparable electronic data record, delivery, and the postpartum period and a copy of any vital records filed in accord with N.J.S.A. 26.

(e) Criteria shall be developed in consultation with the social work department for identifying patients in need of social work services and/or discharge planning and making referrals as needed.

8:43G-19.6 Maternal-fetal transport and neonatal transport

(a) Maternal-fetal transports for maternal management shall only be accepted by a hospital designated as a Regional Perinatal Center. Maternal-fetal transports, when the expected birth weight or gestational age falls below the facility's certified capability for neonatal care, shall be made in accordance with the facility's letter of agreement to utilize the regional transport system within the consortium region.

(b) Each Community Perinatal Center shall establish and implement interhospital transport agreements for patients who require a higher level of care for maternal-fetal management or delivery than the hospital is designated to provide. Such agreements shall be facilitated by the maternal and child health consortium, documented in the facility's letter of agreement with the Regional Perinatal Center and shall be in accordance with the consortium's regional transport system.

(c) Facilities designated as a CPC-Intermediate, CPC-Intensive, or a Regional Perinatal Center shall establish criteria and implement transport agreements with birth centers within their region for patients who require a higher level of care for maternal management delivery, or neonatal management than the birth center is designated to provide. Such agreements shall be facilitated by the maternal and child health consortium and be in accordance with the consortium's regional transport system.

(d) The maternal and child health consortium, in association with the Regional Perinatal Center shall develop transport criteria and implement policies and procedures that establish a regional maternal-fetal transport system which includes, at a minimum, a transport team staffed by health professionals with special training in maternal and fetal care in accordance with hospital policy. This transport system shall be in accordance with the regional perinatal plan.

(e) Each Community Perinatal Center shall establish and implement interhospital transport agreements for neonates who require a higher level of care than the hospital is designated to provide. Such agreements shall be facilitated by the maternal and child health consortium, documented in the facility's letter of agreement with hospitals designated as CPC-Intensive and/or Regional Perinatal Center, and shall be in accordance with the consortium's regional transport system. The transport agreement shall also include provisions for return of the neonate to the sending hospital when the problems that required transport have been resolved.

(f) All Regional Perinatal Centers and CPC-Intensives which have executed letters of agreement to accept neonatal transports shall have, at a minimum:

1. A transport team staffed by health professionals with special training in neonatology;

2. Board eligible or certified anesthesiologists available with special training in the care of neonates;

3. Formal consultative relationship with physicians in the following pediatric subspecialties: anesthesiology, cardiology, hematology/oncology, infectious diseases, nephrology, neurology, pulmonary, radiology, and surgery; and

4. Written policies and procedures specific to the required 30 minute arrival time for the physicians with pediatric subspecialties identified in (f) 3 above.

8:43G-19.7 Obstetric space and environment

(a) The obstetric service shall be physically separate from any service not concerned with obstetric care.

(b) The obstetric service shall have a minimum of 10 obstetric beds.

8:43G-19.8 Obstetric staff education and training

Requirements for the obstetric education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-19.9 (Reserved)

8:43G-19.10 Obstetric continuous quality improvement

(a) There shall be a continuous quality improvement program for obstetrics that is integrated into the hospital continuous quality improvement program and 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.

(b) The continuous quality improvement program for obstetrics should include at least: high-risk screening, review of unattended deliveries, transports to other facilities and return transports, appropriateness of Cesarean sections, use of oxytoxic drugs, prevention of infections in the nursery, fetal morbidity and mortality and maternal and infant morbidity and mortality.

(c) If non-obstetric patients are admitted to the obstetric unit, the continuous quality improvement program shall review cases of all non-obstetric patients transferred from the obstetric unit.

8:43G-19.11 Labor and delivery staff time and availability

(a) There shall be at least one registered professional nurse present whenever a patient is in a labor area. Nurse staffing assignments for patients in active labor shall be determined by patient acuity levels.

(b) All deliveries shall be attended by an obstetrician, a physician with obstetrical privileges, a certified nurse-midwife or an obstetric resident with at least three years of training.

(c) There shall be at least one registered professional nurse attending the patient once she reaches full dilation until she enters the recovery phase of delivery.

(d) If oxytoxics are administered, the following shall occur within one hour prior to administration: the patient shall be examined vaginally by either a physician with obstetric privileges, a certified nurse midwife or an advance practice nurse in accordance with hospital bylaws, and electronic fetal heart rate monitoring shall be initiated.

(e) All obstetrics departments shall have the capability of starting an emergency cesarean section within 30 minutes of the decision to perform a cesarean section.

(f) A health professional certified in neonatal resuscitation shall be available within the obstetrics unit for each delivery.

(g) A pediatrician or pediatric resident shall be present in the delivery room for all high-risk deliveries.

8:43G-19.12 Labor, delivery, anesthesia and recovery patient services

(a) A registry of all births shall be maintained through either the electronic certificate or a maternity log book located in the obstetrics area and shall include the minimum data set required by the Department of Health and Senior Services and in accordance with N.J.S.A. 26:8-30, and N.J.A.C. 8:2.

(b) Obstetrics anesthesia services policies and procedures shall include at least:

1. The obstetric service in consultation with the anesthesia service shall develop and implement written policies and procedures that govern anesthesia services in all labor, delivery and recovery areas. The policies and procedures shall be reviewed annually, revised and implemented.

2. All individuals who administer anesthetic agents to obstetric patients shall be credentialed in accordance with medical staff policies. The physician director of anesthesia services shall participate in the credentialing process and delineation of privileges of all personnel who administer anesthetic agents.

3. The obstetric service, in consultation with the anesthesia service, shall establish protocols governing the use of anesthetic agents for pain management. These shall include the qualifications and responsibilities of persons who administer the use of anesthetic agents for pain management. Policies and procedures shall address the use of patient monitoring equipment and identify the types and levels of agents which may be used for pain management.

4. A preanesthesia note, reflecting evaluation and classification of the patient according to American Society of Anesthesiologists (ASA) Physical Status system, shall be made or certified by the physician administering or supervising the administration of anesthesia and entered into the medical record of each patient who will be administered an anesthetic agent.

5. Anesthetic or pain control agents administered to non-surgical obstetric patients classified for anesthesia risk as an ASA Class I, II or III shall be administered and monitored in accordance with obstetric service policies and procedures governing anesthesia care.

6. Anesthetic or pain control agents administered to non-surgical obstetric patients classified for anesthesia risk as an ASA Class IV, V or Emergency shall be in accordance with the following sections of N.J.A.C. 8:43G-6, Anesthesia Services, as amended:

i. N.J.A.C. 8:43G-6.1, Definitions;

ii. N.J.A.C. 8:43G-6.3(d) through (k), Anesthesia qualifications for administering anesthesia;

iii. N.J.A.C. 8:43G-6.5(b), Anesthesia patient services;

iv. N.J.A.C. 8:43G-6.6, Anesthesia supplies and equipment; safety systems;

v. N.J.A.C. 8:43G-6.7, Anesthesia supplies and equipment; maintenance and inspection; and

vi. N.J.A.C. 8:43G-6.8, Anesthesia supplies and equipment; patient monitoring.

7. For patients undergoing surgical deliveries, including cesarean sections, anesthesia care shall be in accordance with all applicable sections of N.J.A.C. 8:43G-6, Anesthesia Services.

8. There shall be a program of quality assurance for anesthesia care provided in obstetric services that is integrated into the hospital and the anesthesia service quality assurance programs.

(c) There shall be written policies and procedures for the care of patients during the recovery phase of delivery. The policies and procedures shall be reviewed annually, revised as needed, and implemented. These policies and procedures shall include at least:

1. Delineation of the primary medical responsibility for postanesthesia care of the patient;

2. Monitoring of patients, including availability of monitoring equipment, and use of an objective scoring system to determine when the patient has recovered from anesthesia;

3. Requirements for documentation of patient status;

4. Protocol for patient emergencies;

5. Criteria and responsibility for discharge from recovery;

6. Recovery staff qualifications, which shall be as follows:

   i. All registered professional nurses assigned to recovery services shall have training in basic cardiac life support.

   ii. Recovery services shall be staffed at all times by at least one registered professional nurse with critical care training, as defined by the hospital, whenever a patient recovering from a cesarean section and/or classified as ASA Class III, IV, V or Emergency is present;

7. Recovery staff time and availability, which shall be as follows:

   i. There shall be at least two health care personnel, one of whom is a registered professional nurse and the other of whom is either a registered professional nurse or a licensed practical nurse, present in recovery services whenever a patient in the recovery phase of delivery is present. The nurse identified in (c)6ii above may function as the registered professional nurse required herein.

   ii. There shall be a ratio of at least one registered professional nurse present in the recovery service area for every three patients in the recovery phase of delivery; and

8. Recovery patient services, which shall be as follows:

   i. Postanesthesia notes shall be entered into the patient's medical record by a member of the hospital's anesthesia team early in the postoperative period.

   ii. The condition of each patient shall be continually evaluated, with an objective scoring system used to track the patient until she has recovered from anesthesia.

   iii. The patient's vital signs shall be monitored and recorded at least every 15 minutes during recovery.

   iv. Postanesthesia care for patients recovering from a cesarean section and/or classified as ASA Class III, IV, V or Emergency shall also follow 8:43G-35.4(a) through (i).

8:43G-19.13 Postpartum policies and procedures and staff time and availability

(a) At least one registered professional nurse shall be on duty in the postpartum area whenever a patient is present.

(b) Nurse staffing assignments for postpartum patients shall be determined by patient acuity levels.

(c) There shall be written policies and procedures for the care of postpartum patients. The policies and procedures shall be reviewed annually, and revised as needed, and shall include at least the following:

1. Monitoring and documentation of patient's vital signs, condition of uterus, and rate of bleeding.

2. Identification and management of postpartum complications; and

3. Physical care, including care of the perineum and breasts, and ambulation.

8:43G-19.14 Postpartum patient services

(a) The hospital shall provide or arrange for an organized program of education in self-care and newborn care.

(b) If a patient is discharged less than 48 hours after delivery, early follow-up care shall be offered to the patient and arranged on request. The patient's medical record shall include documentation of the offer and the plan for provision of home health services if the offer is accepted.

(c) The hospital shall have staff available to advise postpartum patients in order to prevent difficulties with breast feeding during the hospital stay.

8:43G-19.15 Newborn care policies and procedures

(a) A current roster of physicians, their specific pediatric privileges, and an on-call schedule shall be kept in each nursing unit in newborn care.

(b) A physician or an advanced practice nurse skilled in neonatal assessment shall perform a complete physical examination of the neonate within 24 hours of birth. This examination may serve as both the initial and discharge examination if the neonate is discharged within 24 hours. If the neonate remains in the hospital for more than 24 hours, a second examination shall be performed prior to discharge.

(c) Isolation practices recommended by the Centers for Disease Control shall be used for isolation patients in the newborn nursery, and are incorporated herein by reference. (See CDC Guidelines for Isolation Precautions in Hospitals, publication number PB85927401, available from National Technical Information Services, 5285 Port Royal Rd., Springfield, VA 22161, telephone 703-487-4600.)

(d) The newborn nursery shall identify and report any outbreak of disease, or any single case of a disease as specified in N.J.A.C. 8:57-1.1 through 1.5 also known as Chapter II of the State Sanitary Code.

(e) The hospital shall comply with State laws for screening infants for high risk factors associated with hearing impairment (N.J.S.A. 26:2-101 et seq.), early detection of biochemical disorders in newborns (N.J.S.A. 26:2-110 and 111), reporting congenital defects (N.J.S.A. 268-40.20 et seq.), and completing birth certificates (N.J.S.A. 26:8-28) and death certificates.

(f) Policies and procedures for screening all newborns for hearing impairment, in accordance with N.J.S.A. 26:2-103.1 et seq. shall require that the hospital or birth center:

1. Screen all newborns for hearing impairment using electrophysiologic measures;

2. Screen all newborns for high-risk indicators associated with hearing loss, using criteria established at N.J.A.C. 8:49-1.6, prior to discharge or no later than one month of age;

3. Complete and report to the Department all specified components of the Electronic Birth Certificate, including the hearing screening results within one week of discharge, in accordance with N.J.A.C. 8:19-1.2;

4. Designate a licensed physician or licensed audiologist to oversee the administration of newborn electrophysiologic screening by licensed physicians, licensed audiologists and/or other qualified individuals receiving direction and training by the designated licensed physician or audiologist to administer the electrophysiologic screening; and

5. Establish policies and procedures, in accordance with N.J.A.C. 8:19-1.3 and 1.4 for the provision of follow-up services for newborns that do not pass or receive electrophysiologic screening in one or both ears and for those that are identified as being at risk of developing a hearing loss.

(g) Policies and procedures for the early detection of biochemical disorders in newborn infants, including at least hypothyroidism, galactosemia, and phenylketonuria, pursuant to N.J.S.A. 26:2-110 and 111, shall include, but not be limited, to the following:

1. Collection of blood specimens from newborn infants on collection kits provided by the Department;

2. Collection of blood specimens 24 hours after the newborn infant's first feeding or 48 hours after the newborn infant's birth or upon the newborn infant's discharge from the facility, whichever comes first;

3. Development of a system within the facility for the submission of blood specimens to arrive at the Department's laboratory no later than 96 hours after the newborn infant's birth;

4. Designation of a staff member(s) to be responsible for receiving verbal and written positive screening test results and documenting the results in the newborn infant's medical record; and

5. Provision of written information, provided by the Department and/or the facility, to all parents and physicians regarding the testing of biochemical disorders and the possibility of incorrect screening test results if the blood specimen is not collected.

(h) The newborn's medical record shall include at least:

1. A summary of the mother's obstetric and relevant medical history;

2. Anesthesia, analgesia, and medications given to the mother;

3. Reasons for induction of labor and operative procedures, if performed;

4. Date and time of birth and copies of all vital records;

5. Birth weight and length;

6. Condition of the newborn at birth, including the one-and five-minute Apgar scores, time of sustained respirations, details of any physical abnormalities, and any pathological states observed and treatment given before transfer to the nursery;

7. Any abnormalities of the placenta and cord vessels;

8. Length of gestation;

9. Procedures performed in the delivery room;

10. A record of the newborn assessment, performed by a physician or registered professional nurse upon the newborn's admission to the nursery;

11. A plan of care;

12. A record of the initial physical examination, performed, signed, and dated by a physician;

13. A record of a physical examination on discharge or transfer to another facility, including head circumference, signed, and dated by a physician; and

14. Documentation of eye prophylaxis, as recommended by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists for ophthalmia neonatorum, administration of any other medication or treatment and response, and performance of inborn error and hearing screenings.

8:43G-19.16 Normal newborn nurse staff qualifications, staff time and availability

(a) Hospitals designated as a CPC-Basic may provide care to neonates born greater than 2,499 grams or at least 36 weeks gestation. The only exception to this criteria is if it has been documented in the medical record that the neonate was expected to meet the weight and age criteria and the neonate does not require a higher level of care than otherwise specified for a CPC-Basic. Service restrictions placed on CPC-Basic include:

1. Mechanical ventilatory support shall not be provided except for resuscitative measures; and

2. Total parenteral nutrition shall not be provided.

(b) The physician director of newborn care in hospitals designated as a CPC-Basic shall be board certified in pediatrics.

(c) There shall be a nurse manager of the normal newborn nursery who may also function as the nurse manager of the obstetric service. This individual shall be a registered professional nurse with, at a minimum:

1. Three-years of experience in inpatient neonatal services within the five years immediately preceding the date of appointment;

2. Educational preparation in maternal-fetal neonatal nursing, in accordance with hospital policy; and

3. Completion of 24 contact hours of maternal-fetal or neonatal nursing approved by a nationally recognized nurse education accrediting body every three years.

(d) There shall be a health professional certified in neonatal resuscitation available within the unit at all times.

(e) The normal newborn nursery shall be covered at all times by a pediatrician, family practice physician with pediatric privileges, or certified neonatal or pediatric nurse practitioner who is either present in the hospital or available by telephone and able to arrive within 30 minutes of being, summoned, under normal transportation conditions.

(f) The normal newborn nursery shall have a registered professional nurse present whenever a neonate is in the newborn nursery. Additional staffing, assignments shall be determined by acuity levels appropriate to infants.

(g) The normal newborn nursery shall have at least one registered professional nurse to every eight neonates. However, so long as one registered nurse is on duty as required by (d) above, licensed practical nurses may be used to comply with the nurse:infant ratio requirement.

8:43G-19.17 Intermediate nursery staff qualifications, staff time and availability

(a) Hospitals designated as a CPC-Intermediate may provide care to neonates born greater than 1,499 grams or at least 32 weeks gestation. The only exception to this criteria is if it has been documented in the medical record that the neonate was expected to meet the weight and age criteria and the neonate does not require a higher level of care than otherwise specified for a CPC-Intermediate. Service restrictions placed on CPC-Intermediate include:

1. In no case shall continuous or intermittent positive pressure ventilatory support be administered to an intubated neonate for more than 48 hours, except in cases where authorization has been received from the neonatologist on-call at the Regional Perinatal Center or the CPC-Intensive and the CPC-Intermediate has demonstrated the ability to intubate and is able to hourly monitor the partial pressure of oxygen in the neonate's blood. Authorization from the neonatologist on-call at the Regional Perinatal Center or the CPC-Intensive shall be obtained on a daily basis and shall be documented in the medical record; and

2. All neonates, regardless of birth weight, who require surgery, or other highly specialized services shall be transported to a higher level facility capable of providing the care.

(b) The physician director of newborn care in hospitals designated as a CPC-Intermediate shall be board certified in pediatrics.

(c) There shall be a nurse manager of the intermediate nursery who meets the qualifications of the nurse manager specified in N.J.A.C. 8:43G-19.16(c). This individual may also function as the nurse manager of the obstetric service.

(d) There shall be a health professional certified in neonatal resuscitation available within the unit at all times.

(e) The intermediate nursery shall be covered at all times by a board eligible or certified pediatrician with certification and/or training and experience in neonatal medicine or a certified neonatal or pediatric nurse practitioner who is either present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned under normal transportation conditions. A physician who has training and experience in neonatal medicine or a certified neonatal or pediatric nurse practitioner shall be present in the hospital whenever a neonate is receiving any form of positive pressure oxygen therapy.

(f) The intermediate nursery shall have at least one registered professional nurse to every four infants requiring intermediate care services. Additional staffing assignments shall be determined by the acuity levels of the infants.

8:43G-19.18 Neonatal intensive care nursery staff qualification, staff time and availability

(a) A CPC-Intensive may provide care to neonates greater than 999 grams and at least 28 weeks gestation. A CPC-Intensive may provide care to neonates born in the facility who are below the specified weight and age criteria only if the infant does not require a higher level of care than otherwise specified for CPC-Intensive and if it has been documented in the medical record that the birth was expected to meet the weight and age criteria. A CPC-Intensive may provide long term ventilatory support and total parenteral nutrition.

(b) A Regional Perinatal Center may provide care to all neonates regardless of weight and gestational age and may provide long term ventilatory support and total parenteral nutrition.

(c) The physician director of the neonatal intensive care nursery in a CPC-Intensive and a Regional Perinatal Center shall be board certified in pediatrics with certification in neonatal medicine.

(d) There shall be a nurse manager of the neonatal intensive care nursery in CPC-Intensive and Regional Perinatal Centers who meets the qualifications of the nurse manager specified in N.J.A.C. 8:43G-19.16(c).

(e) There shall be a health professional certified in neonatal resuscitation available within the unit at all times.

(f) The neonatal intensive care nursery in CPC-Intensive and Regional Perinatal Centers shall be covered at all times by a neonatal fellow or a board eligible or certified pediatrician with training and experience in neonatal medicine, or a certified neonatal or pediatric nurse practitioner who is present in the hospital.

(g) The neonatal intensive care nursery in CPC-Intensive and Regional Perinatal Centers shall be covered at all times by a board certified pediatrician with certification in neonatal medicine, who is either present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions. This physician may also serve as the physician director of the neonatal intensive care nursery.

(h) The neonatal intensive care nursery shall have at least one registered professional nurse to every two neonates requiring intensive care services. Additional staffing assignments shall be determined by the acuity levels of the infants.

8:43G-19.19 Newborn care patient services

(a) The newborn service shall provide for immediate resuscitation of the newborn, including at least:

1. Short-term ventilation with laryngoscope, endotracheal tube, and bag-valve-mask;

2. Oxygen administration;

3. Intravenous therapy;

4. Temperature control; and

5. Infusion equipment.

(b) Each bassinet and incubator in the nursery shall bear the identification of the newborn to whom it is assigned. This identification shall include at least the newborn's last name, sex, date, time of birth, feeding method, the mother's first and last names, and the physician's name.

(c) There shall be a system for the identification of each newborn immediately upon delivery and during the hospital stay, and for maintaining the security of the newborn.

(d) There shall be a system for verifying the identity of mothers and infants whenever an infant is removed from, or returned to, the nursery.

(e) The hospital shall assist Medicaid-eligible patients, including newborns, by expediting the verification and documentation of hospital-based services. For example, the hospital may issue a document of birth for infants prior to discharge (including hospital of birth, mother's name, mother's Social Security number, newborn name, date of birth, and sex) to enable infants to receive Medicaid services from county welfare offices before an official birth certificate is issued.

8:43G-19.20 Newborn care supplies and equipment

(a) Each room used as a nursery accessory room shall be equipped with at least three foot-controlled, covered, and labeled receptacles: one for the disposal of wet or soiled diapers, one for the disposal of trash, and one for the sanitary disposal of linens other than wet or soiled diapers. Disposable liners shall be used in the diaper and trash receptacles.

(b) Bassinets and equipment not in routine use shall be stored outside the nurseries or nursery accessory rooms.

(c) Individual supplies, linen, and equipment shall be provided for each infant.

(d) If newborns are weighed on a common scale, an impervious cover that completely covers the surface of the scale pan shall be used and changed after each newborn is weighed.

(e) Prepackaged formula shall be used within the time period designated on the package.

(f) Each incubator and bassinet shall be cleaned and disinfected after each time a newborn occupying it is discharged. The detergent and disinfectant used shall be registered by the U.S. Environmental Protection Agency.

(g) Provisions shall be made for the emergency repair and replacement of equipment in the newborn nursery.

8:43G-19.21 Scope of nurse-midwifery standards

The standards in N.J.A.C. 8:43G-19.22 through 19.26 shall apply only to hospitals that have a separate, designated service or unit for nurse-midwifery. Hospitals which do not have a separate, designated service or unit for nurse-midwifery but grant obstetrical privileges to nurse-midwives are not required to follow N.J.A.C. 8:43G-19.24(a) and 19.25.

8:43G-19.22 Nurse-midwifery structural organization

Nurse-midwifery services shall be organized as part of the obstetric service. The physician director of obstetrics shall be responsible for assuring that nurse-midwifery services conform with applicable rules and hospital policies and procedures.

8:43G-19.23 Nurse-midwifery policies and procedures

(a) Nurse-midwifery services shall be based on written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies and procedures shall include mechanisms by which medical staff in the obstetric and newborn services consult with and assist nurse-midwives.

(b) The hospital shall delineate and fully review the privileges and credentials of each nurse-midwife periodically.

(c) There shall be standing orders for nurse-midwifery services.

8:43G-19.24 Nurse-midwifery staff qualifications

(a) There shall be a certified nurse-midwife who serves as director of nurse-midwifery services, coordinates and is responsible for all nurse midwifery services provided in the hospital, and monitors the quality of nurse-midwifery care.

(b) All nurse-midwives practicing in the hospital shall be registered professional nurses and currently certified by the New Jersey Board of Medical Examiners.

8:43G-19.25 Nurse-midwifery staff education

Requirements for the nurse-midwifery education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-19.26 Nurse-midwifery quality assurance methods

The quality assurance program for nurse-midwifery services shall include physicians and nurse-midwives and shall monitor at least high-risk screening, transfers and return transfers, and mortality and morbidity by birth weight.

8:43G-19.27 Obstetric/non-obstetric mix program

(a) If the hospital places non-obstetric patients on the obstetric unit, it shall establish written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies shall include:

1. Criteria and procedures for admission of female non-obstetric patients;

2. Criteria for non-admission;

3. Method for ensuring that no obstetric patient is excluded from the obstetric service; and

4. Protocols for cultures of non-obstetric patients, including the type of cultures, when, and under what circumstances they are performed.

(b) A log book of non-obstetric patients admitted to the obstetric service shall be maintained. This log book shall include, in addition to patient's name, at least:

1. Dates of hospital admission and discharge;

2. Admission and discharge diagnoses;

3. Date and type of surgery, if performed, including associated procedures, and name of surgeon;

4. Morbidity and cause, if applicable;

5. Destination, date, and reason for transfer to other units of the hospital; and

6. Medical record number.

(c) An admission check sheet and questionnaire shall be filled out upon admission to the hospital for every non-obstetric patient admitted to the obstetric service, and shall be included in the patient's medical record.

8:43G-19.28 Obstetric/non-obstetric mix patient services

(a) A non-obstetric patient shall not be admitted to the obstetric service if she has any of the following conditions:

1. An oral temperature of 100.4 degrees Fahrenheit or higher upon admission;

2. Substance abuse or misuse;

3. A history of household contacts with staphylococcal infection or other contagious diseases that have occurred within one month prior to admission;

4. Known malignancy requiring the use of radioactive therapeutics;

5. Has received antibiotics other than prophylactic antibiotics, with the exception of local application of antibiotics such as bladder irrigation or local vaginal preparation during the two-week period prior to admission; or

6. Has received preoperative prophylactic antibiotics more than six hours prior to surgery or more than 72 hours following surgery.

(b) A non-obstetric patient shall be transferred from the obstetric service if she:

1. Has a fever as defined by hospital policy;

2. Has any sign of infection, including infection discovered at the time of surgery.

(c) All surgical procedures performed on non-obstetric patients on the obstetric service shall be performed in the operating suite.

(d) The same visitors policy shall apply to both obstetric and non-obstetric patients on the mixed obstetric service.

8:43G-19.29 Physical plant general compliance for new construction, alteration or renovation for newborn care

Physical plant standards for newborn care areas shall be in compliance with N.J.A.C. 5:23-3.2 of the New Jersey Uniform Construction Code.

8:43G-19.30 Functional areas for newborn care

(a) Functional areas for newborn care shall be as follows:

1. Neonatal Resuscitation Area or Room;

2. Admission/observation/Continuing Care Nursery or Area;

3. Normal Newborn Nursery or Holding Nursery;

4. Infectious Isolation Nursery;

5. Intermediate Care Nursery; and

6. Neonatal Intensive Care Nursery.

8:43G-19.31 General newborn care functional area requirements

(a) General requirements for functional areas designated in N.J.A.C. 8:43G-19.36 shall be as required in (b) through (s) below.

(b) Provisions shall be made for indirect lighting and high-intensity lighting in all nurseries. The level of general lighting shall be adjustable to satisfy diagnostic and procedural requirements.

(c) Viewing windows shall be extensive throughout the newborn suite. Exterior windows shall be energy efficient and insulated.

(d) Newborn care areas shall have oxygen and medical air piped from a central source in accordance with National Fire Protection Association 99 Standard for Health Care Facilities (NFPA 99), published by the NFPA, Box 9101, One Batterymarch Park, Quincy, MA 02269-9101, incorporated herein by reference.

(e) Oxygen air and suction systems shall have chime alarms to signal loss of suction or low oxygen and air supply.

(f) A temperature of 75 degrees Fahrenheit and a relative humidity of 50 percent shall be maintained.

(g) An emergency call system shall be provided in each nursery.

(h) A free-standing handwashing sink shall be provided with hands free control in a bowl large and deep enough to prevent splashing. A liquid soap dispenser and disposable towel dispenser shall be provided at each sink.

(i) Each infant station shall be supplied by at least two branch circuits.

(j) Ventilation requirements shall be in accordance with Section 7.31.D of the "Guidelines for Construction and Equipment of Hospital and Health Care Facilities" (The American Institute of Architects Press), 1996-97 edition, as amended and supplemented, published by the AIA, 1735 New York Ave. NW, Washington, DC 20006, (202) 626-7475, incorporated herein by reference.

(k) The newborn nursery shall be a closed unit, physically segregated from other areas.

(l) There shall be a waiting room available in the obstetrics area.

(m) There shall be a toilet and telephone available for use by the public in the obstetrics area.

(n) A separate room or area within the nursery workroom or clean utility room shall be provided for the storage of infant formula and breast milk. A refrigerator/freezer used only for the storage of breast milk and formula shall be provided.

(o) There shall be at least one staff office and a staff lounge in, or adjacent to, the obstetrics area.

(p) There shall be a soiled utility room which shall contain the following:

1. A clinical sink;

2. A work counter;

3. A handwashing sink;

4. Liquid soap dispensers;

5. A paper towel dispenser; and

6. Space for storage of soiled equipment, soiled linen and trash receptacles.

(q) There shall be a neonatal unit clean work area or room which shall contain:

1. A counter with cabinets;

2. A refrigerator;

3. A handwashing sink;

4. Liquid soap dispensers;

5. A paper towel dispenser; and

6. Space for storage of clean equipment and clean linen.

(r) There shall be a housekeeping room in the obstetrics area which shall contain a floor receptor or service sink and provisions for storage of supplies and housekeeping equipment.

(s) There shall be an administrative center or nurses station which may be combined with or include a center for reception and communication. This area shall be designed to permit visual observation into the newborn nurseries and storage space.

8:43G-19.32 Neonatal unit resuscitation area

(a) There shall be an infant resuscitation area for each cesarean/delivery room. This area shall be located either within the cesarean/delivery room or in a separate but immediately accessible room. The square footage requirement for the infant resuscitation area is as follows:

1. If the resuscitation area is located within the cesarean/delivery room, a minimum of 40 square feet of additional clear floor area shall be provided; or

2. If the resuscitation area is located in a separate room, this room shall have a minimum of 150 square feet of clear floor area and shall also contain a free-standing handwashing sink.

(b) The resuscitation area shall have a minimum of:

1. An overhead source of radiant heat;

2. A large wall clock with a clearly visible second hand;

3. A flat working surface for charting;

4. A table or flat surface for trays;

5. One oxygen outlet;

6. One medical air outlet; and

7. One suction outlet.

(c) A minimum of six single or three duplex electrical outlets shall be provided in each resuscitation area or room. If a separate resuscitation room is provided, an electrical outlet to accommodate a portable X-ray machine shall also be provided.

8:43G-19.33 Neonatal admission/observation/continuing care nursery or area

(a) There shall be an admission/observation/continuing care nursery available for infants who are stable but require frequent feedings or close observation. This nursery may be located in the normal newborn nursery or may be provided in a separate area.

(b) If the admission/observation/continuing care nursery is provided in a separate area, the following physical plant requirements shall be followed:

1. There shall be a minimum of 24 square feet of floor area exclusive of auxiliary work areas for each infant station with a minimum of three feet between bassinets;

2. One oxygen outlet, one medical air outlet and one vacuum outlet shall be provided for each infant station;

3. Two duplex electrical receptacles shall be provided for each infant station;

4. A hands-free handwashing sink shall be provided in the room; and

5. This area shall be served by a connecting workroom.

8:43G-19.34 Normal newborn nursery or holding nursery

(a) There shall be either a normal newborn nursery or a holding nursery. A normal newborn nursery shall be located close to the postpartum unit and shall be inaccessible to unrelated traffic. If a holding nursery is provided, it shall meet the requirements of (b) through (g) below.

(b) The number of bassinets shall equal the number of licensed obstetric beds.

(c) A minimum of 24 square feet for each bassinet exclusive of auxiliary work areas shall be provided, with three feet between bassinets in all directions from edge of one to the other with a separate aisle four feet wide, in addition to the required bed space.

(d) A maximum of 16 bassinets shall be permitted in one normal newborn nursery.

(e) One oxygen outlet, one medical air outlet and one vacuum outlet for each infant station shall be provided.

(f) Oxygen air and suction systems shall have chime alarms to signal loss of suction or low oxygen and air supply.

(g) Two duplex wall-mounted electrical receptacles shall be provided for every infant station.

(h) A free-standing handwashing sink with hands free controls shall be provided, with a minimum of one sink at each end of the nursery, and at a ratio of one sink for every six infant stations.

(i) There shall be at least one multi-purpose room available for consultation, breast feeding, lactation training and conferences.

(j) A soiled utility room shall be provided.

(k) A clean utility room or area shall be provided.

(l) An examination and treatment room or work area shall be provided within the suite. Such room or work area shall contain a work-counter, storage, and a free-standing sink equipped for handwashing with foot control.

(m) Storage facilities for the newborn nursery shall be as follows:

1. There shall be storage space for items such as linens and formula within the area;

2. There shall be an equipment storage room for large items of equipment; and

3. There shall be storage space within the nursery area for an emergency cart.

(n) The normal newborn nursery shall be served by a connecting workroom.

(o) There shall be separate changing areas for men and women, located so that staff are able to change clothing prior to entering the clean area of the neonatal nursery unit.

(p) A scrub gowning area shall be provided for staff and housekeeping personnel at the entrance of each nursery, but separate from the work area. The scrub gowning area shall contain a free-standing handwashing sink with hands free controls and a bowl large enough to prevent splashing. The following shall be provided:

1. Racks, hooks or lockers for storage of street clothes and personal items;

2. Cabinets with clean gowns; and

3. A receptacle for used gowns.

8:43G-19.35 Infectious nursery

(a) An infectious isolation nursery shall be available in at least one level of nursery care.

(b) The infectious isolation nursery shall be an enclosed and separate room within the nursery unit with provision for observation of the neonate from adjacent nurseries or control area.

(c) The isolation nursery shall be served by an anteroom that contains a freestanding handwashing sink with hands free controls and separate storage facilities for clean and soiled materials and gowns.

(d) One oxygen outlet, one medical air outlet and one vacuum outlet shall be provided for each infant station.

(e) Two duplex receptacles shall be provided for each infant station.

8:43G-19.36 Intermediate care nursery

(a) The intermediate care nursery shall be a separate nursery designed exclusively for the care of intermediate level infants located away from general hospital traffic and close to the delivery room and the intensive care nursery, if provided.

(b) Each infant patient station shall have a minimum of 50 square feet of floor space, excluding ancillary space for storage. There shall be four feet between incubators or bassinets with a separate aisle five feet wide, in addition to required bed space.

(c) Each infant care station shall have two oxygen outlets, two medical air outlets and two vacuum outlets.

(d) Oxygen air and suction systems shall have chime alarms to signal loss of suction or low oxygen and air supply.

(e) Four duplex receptacles shall be provided for each station.

(f) A handwashing sink with hands free controls, soap dispenser and towel dispenser shall be provided at the entrance of the intermediate care nursery. One sink shall be provided for every three infant care stations within the nursery.

(g) A soiled utility room shall be provided.

(h) A clean utility room or area shall be provided.

(i) Storage facilities for the intermediate care nursery shall be as follows:

1. There shall be storage for supplies needed for immediate use for each infant care station; and

2. There shall be at least 20 square feet of floor space for equipment for each infant care station immediate accessible to the nursery.

(j) There shall be at least two multi-purpose rooms available for consultation, breast feeding, lactation training and conferences.

8:43G-19.37 Neonatal intensive care nursery

(a) The neonatal intensive care nursery shall be near the cesarean/ delivery room and shall be removed from routine hospital traffic.

(b) The intensive care nursery shall provide 100 square feet per bassinet or incubator allowing a minimum of six feet between bassinets and at a minimum, an eight foot wide aisle.

(c) There shall be three oxygen outlets, three medical air outlets and four vacuum outlets for each infant care station.

(d) Oxygen air and suction systems shall have chime alarms to signal loss of suction or low oxygen and air supply;

(e) There shall be seven duplex receptacles for each infant care station.

(f) Storage facilities for the neonatal intensive care nursery shall be as follows:

1. There shall be storage and counter space for immediate use within the infant's room for each infant care station; and

2. There shall be at least 30 square feet of floor space for equipment for each infant care station immediately accessible to the nursery.

(g) A soiled utility room shall be provided.

(h) A clean utility room or area shall be provided.

(i) A free-standing handwashing sink with hands free controls shall be provided at the entrance to the intensive care nursery. One sink shall be provided for every three infant care stations within the nursery.

(j) There shall be on-call room(s) for staff on the same floor of the hospital with an adjoining toilet, lavatory and shower.

(k) There shall be at least three multi-purpose rooms available for consultation, breast feeding, lactation training and conferences.

8:43G-19.38 Shared services

(a) If the intermediate care and neonatal intensive care nurseries are located in the same suite, then the following services may be shared:

1. Janitor's closet;

2. Soiled utility;

3. Clean utility;

4. The three multi-purpose rooms required for a intensive care nursery;
5. Storage room;
6. Male/female staff lockers, lounge and toilets; and
7. On-call room.

8:43G-19.39 (Reserved)

8:43G-19.40 (Reserved)

8:43G-19.41 (Reserved)

8:43G-19.42 (Reserved)

8:43G-19.43 (Reserved)

8:43G-19.44 (Reserved)

8:43G-19.45 (Reserved)

8:43G-19.46 (Reserved)

8:43G-19.47 (Reserved)

8:43G-19.48 (Reserved)

8:43G-19.49 (Reserved)

8:43G-19.50 (Reserved)

8:43G-19.51 (Reserved)

8:43G-19.52 (Reserved)

8:43G-19.53 (Reserved)

SUBCHAPTER 20. EMPLOYEE HEALTH

8:34G-20.1 Employee health policies and procedures

(a) Employee health 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 shall be readily available for employees to review and include at least the following:

1. The content and frequency of employee health examinations performed by a registered professional nurse, physician, or other qualified medical personnel as defined at N.J.A.C. 8:43G-20.2(a);

2. Precautionary measures to prevent the transmission of communicable diseases from employees to patients;

3. Requirements for a physician note approving an employee's return to work after an absence due to a communicable disease; and

4. Clinical restrictions for employees exposed to rubella or rubeola who are seronegative and unvaccinated.

8:43G-20.2 Employee health services

(a) Each new employee shall receive an initial health evaluation, which includes at least a documented history, which may be performed by a registered professional nurse, physician, or other qualified personnel (defined as a licensed physician assistant or a certified nurse practitioner/clinical nurse specialist), and a physical examination.

(b) Employee health records shall be maintained for each employee. Employee health records shall be confidential, and kept in the employee health office separate from personnel records.

(c) The employee health record shall include documentation of all medical screening tests performed and the results.

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

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

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

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

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

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

iii. Exceptions:

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

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

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

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

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

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

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

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

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

(e) Rubella screening: Each employee, including members of the medical staff employed by the hospital, shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test within six months of the effective date of this subchapter. The only

exceptions are employees who can document seropositivity from a previous rubella screening test or who can document innoculation with rubella vaccine, or when medically contraindicated.

1. Each new employee, including members of the medical staff employed by the hospital, shall be given a rubella screening test upon employment.

(f) Measles (Rubeola) screening: Each employee, including members of the medical staff employed by the hospital, born in 1957 or later shall be given a measles (rubeola) screening test using the Hemagglutination inhibition test or other rubeola screening test. The only exceptions are employees who can document receipt of live measles vaccine on or after their first birthday, physician-diagnosed measles, or serologic evidence of immunity.

1. Each new employee, including members of the medical staff employed by the hospital, born in 1957 or later shall be given a rubeola screening test, upon employment.

(g) The hospital shall offer rubella and rubeola vaccination to all employees and medical staff.

(h) The hospital shall maintain a list identifying the name of each employee who is seronegative and unvaccinated.

(i) The hospital shall comply with the reporting requirements of the Department of Health and Senior Services Division of Epidemiology, Environmental and Occupational Health Services for tuberculin and rubella test results, pursuant to N.J.A.C. 8:57. Information regarding testing and reporting can be obtained from:

New Jersey State Department of Health and Senior Services
Communicable Disease Control Services
P.O. Box 369
Trenton, NJ 08625-0369

(j) The hospital shall provide initial healthcare for employees who become ill or have a work-related illness or injury. "Initial health care" means that the ill or injured employee shall be seen and evaluated by a physician, licensed physician assistant, or certified nurse practitioner/clinical nurse specialist and stabilized prior to referral for further treatment, as appropriate.

(k) Personnel who are absent from work because of any reportable communicable disease, infection, or exposure to infection, as defined in N.J.A.C. 8:57, shall be excluded from working in the hospital until they have been examined by a physician and certified by the physician as no longer endangering the health of patients or employees. If the absence is less than three full days, the hospital's employee health nurse may certify that the employee is able to return to work.

(l) The hospital shall have a program addressing the needs of impaired employees, which at a minimum shall include methods or mechanisms to identify and refer impaired employees to rehabilitation programs.

8:43G-20.3 (Reserved)

8:43G-20.4 Employee health education

Requirements for the employee health education program shall be as provided in N.J.A.C. 8:43G-5.9

8:43G-20.5 (Reserved)

8:43G-20.6 Employee health continuous quality improvement methods

There shall be a program of continuous quality improvement for employee health that is integrated into the hospital quality improvement program and includes regularly collecting and analyzing data to help identify employee health problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

SUBCHAPTER 21. ONCOLOGY

8:43G-21.1 Scope of oncology standards

The standards in this subchapter shall apply only to hospitals that have a separate, designated patient care unit for oncology.

8:43G-21.2 Oncology structural organization

(a) There shall be a multidisciplinary cancer committee, chaired by a physician, that is responsible for at least the development of oncology policies and procedures, tumor review, and tumor registry.

(b) There shall be a formal mechanism for communication between the oncology service and each of the following clinical areas: nursing, dietary, social work, and pharmacy.

8:43G-21.3 (Reserved)

8:43G-21.4 Oncology policies and procedures

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

1. Criteria for admission;

2. Guidelines for mixing chemotherapy, when performed on the unit, that reference Occupational Safety and Health Administration (OSHA) guidelines: "Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," OSHA Instruction PUB 8-1.1, PB 89203301 Office of Occupational Medicine;

3. Guidelines for administering chemotherapy that follow national Oncology Nursing Society guidelines; available from the Oncology Nursing Society, 1016 Greentree Road, Pittsburgh, PA 15220-3125, telephone 412-921-7373.

4. Training of nursing and housekeeping staff in the disposal of chemotherapeutic agents;

5. Use, handling, storage, and disposal of specific chemicals, agents, and body wastes;

6. Assuring informed consents to chemotherapy; and

7. Psychological/social and spiritual aspects of patient care.

(b) There shall be written visiting policies for patients that allow for visits by children and 24-hour visitation rights for designated visitors.

8:43G-21.5 Oncology staff qualifications

(a) There shall be a clinical coordinator with responsibility to administer the program of care who is a registered professional nurse with the equivalent of two years of full-time experience in oncology.

(b) There shall be a clinical resource person who is a registered professional nurse with the equivalent of two years of clinical experience in oncology who is available to the unit.

8:43G-21.6 (Reserved)

8:43G-21.7 Oncology staff time and availability

(a) A member of social work services shall be assigned to the unit to provide psychosocial services, assist with discharge planning, and provide information regarding financial aspects of care.

(b) A registered dietitian shall be assigned to the oncology service.

8:43G-21.8 (Reserved)

8:43G-21.9 Oncology patient services

(a) There shall be multidisciplinary patient care team meetings that take place on a regularly scheduled basis and include at least a physician or physician's appointed designee, a nurse, a social worker, a dietitian, and other disciplines as necessary.

(b) Patient and family teaching shall be provided in any case where the patient and family are in need of and able to receive instruction.

(c) Criteria shall be developed in consultation with the social work department for identifying patients in need of social work services and/or discharge planning and making referrals as needed.

(d) There shall be a system to refer patients, family, and staff to in-house and community support groups and services.

8:43G-21.10 (Reserved)

8:43G-21.11 Oncology space and environment

(a) There shall be food-warming facilities on the unit for use by patients and their families.

(b) Single bedrooms shall be available as needed to accommodate patients with neutropenia, bone marrow transplants, or radiation implants.

8:43G-21.12 (Reserved)

8:43G-21.13 Oncology supplies and equipment

A Class 2 Vertical Laminar Air Flow Hood shall be used during the preparation of all chemotherapy on the unit. Occupational Safety and Health Administration (OSHA) guidelines: "Work Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," OSHA Instruction PUB 8-1.1, Office of Occupational Medicine, shall be used to develop procedures for preparing chemotherapy.

8:43G-21.14 (Reserved)

8:43G-21.15 Oncology staff education

Requirements for the oncology education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-21.16 (Reserved)

8:43G-21.17 Oncology continuous quality improvement methods

There shall be a program of continuous quality improvement for oncology that is integrated into the hospital continuous quality improvement program and 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.

SUBCHAPTER 22. PEDIATRICS

8:43G-22.1 Scope of pediatric and pediatric intensive care standards

The standards in this subchapter shall apply only to hospitals that have a separate, designated unit or service for pediatrics and pediatric intensive care.

8:43G-22.2 Pediatrics and pediatric intensive care policies and procedures

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

1. The age below which all patients must be admitted to a pediatric service;

2. The age above which patients are admitted to a pediatric service only at the discretion of the physician director of the service;

3. Admission and discharge criteria specific to the service;

4. A visitors policy that allows for 24 hour visitation by designated visitors and specifies the number of visitors permitted each patient at any one time;

5. Criteria for those pediatric patients who require a pediatric consultation or case management by a pediatrician;

6. Infection control protocols;

7. Protocols for specific types of patient emergencies;

8. An emergency transfer policy which specifies mechanisms for transport of pediatric patients requiring specialized or intensive care services to facilities providing such care; and

9. Safety measures for the purpose of preventing electrical and bodily injury to patients.

(b) Every patient under 18 years of age who is admitted temporarily to the adult intensive care unit shall receive a pediatric consultation.

(c) If the hospital does not have pediatric intensive care services, the hospital must state the conditions under which a pediatric patient may be temporarily admitted to the adult intensive care unit. The hospital shall establish and implement protocols for the stabilization and transfer of these patients to a facility providing pediatric intensive care services.

(d) The pediatric services shall participate in developing anesthesia and pain management policies for infants and children.

8:43G-22.3 Pediatrics and pediatric intensive care patient services

(a) The nursing assessment of each pediatric patient shall include assessment of the patient's developmental needs. Nursing care shall be structured around this assessment.

(b) All standard blood studies on pediatric patients shall use at least micro methodology.

(c) There shall be documented evidence of pediatric medical and nursing staff participation in the development of policies and procedures of pediatric patients in any department where pediatric patients may receive treatment. At a minimum, this shall include the areas of dietary, emergency department, laboratory, pharmacy services, radiology, rehabilitation, and social work.

(d) Criteria shall be developed in consultation with the social work department for identifying patients in need of social work and/or discharge planning and making referrals as needed.

(e) The parents or guardians of pediatric patients shall be included in the development of the nursing patient plan of care.

8:43G-22.4 (Reserved)

8:43G-22.5 Pediatrics and pediatric intensive care supplies and equipment

Emergency equipment shall be child-sized or adaptable for children.

8:43G-22.6 Pediatrics and pediatric intensive care staff education

Requirements for the pediatrics and pediatric intensive care education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-22.7 (Reserved)

8:43G-22.8 Pediatric and pediatric intensive care continuous quality improvement methods

There shall be a program of continuous quality improvement for each pediatric service that is integrated into the hospital continuous quality improvement program and 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. The data shall include, but not be limited to, the number of pediatric admissions to the adult intensive care unit.

8:43G-22.9 Scope of pediatrics standards

The standards in N.J.A.C. 8:43G-22.10 through 22.12 shall apply only to hospitals that have a separate, designated unit or service for pediatrics.

8:43G-22.10 Pediatric staff qualifications

(a) The physician director of the pediatric service shall be board certified in pediatrics.

(b) The nurse with administrative responsibility for nursing care in pediatrics shall be a registered professional nurse with at least three years of experience in pediatrics.

8:43G-22.11 (Reserved)

8:43G-22.12 Pediatrics space and environment

(a) A minimum of 10 percent of the beds used for pediatric care shall be capable of functioning as isolation rooms.

(b) Each pediatric unit shall have at least one playroom with recreation equipment and child-size tables and chairs.

(c) There shall be an adult supervising when children under seven years of age are present in the recreation room or playroom.

8:43G-22.13 Scope of pediatric intensive care standards

The standards in N.J.A.C. 8:43G-22.14 through 22.22 shall apply only to hospitals that have a separate, designated unit or service for pediatric intensive care.

8:43G-22.14 Pediatric intensive care structural organization

There shall be a multidisciplinary pediatric intensive care committee or its equivalent that includes at least representatives of nursing, medical staff, administration, respiratory therapy, and social work. This committee shall meet regularly to discuss unit administration and ways of improving interdisciplinary communication on the pediatric intensive care unit.

8:43G-22.15 Pediatric intensive care staff qualifications

(a) There shall be a full-time physician director of the pediatric intensive care service who is board certified or board eligible in pediatric critical care.

(b) The pediatric intensive care unit shall be covered at all times by at least one physician, present in the hospital or on call, who is board certified or board eligible in pediatrics and has either five years of experience in pediatrics or has completed a fellowship in a pediatric subspecialty.

(c) The pediatric intensive care unit shall have physicians with each of the following pediatric subspecialties on staff: anesthesiology, cardiology, hematology/oncology, infectious diseases, nephrology, neurology, pulmonary, radiology, and surgery.

(d) The pediatric intensive care unit shall have a formal consultative relationship with physicians in the following pediatric subspecialties: endocrinology, gastroenterology, neurosurgery, otolaryngology, and urology.

(e) Specific privileges for physicians who admit patients to the pediatric intensive care unit shall be delineated by the hospital with participation of the physician director of the pediatric intensive care unit.

(f) The nurse with administrative responsibility for nursing in the pediatric intensive care unit shall be a registered professional nurse with specialized training in pediatric critical care and at least three years of experience in a pediatric intensive care unit.

(g) There shall be a health professional trained in resuscitation of children available within the unit at all times.

(h) Effective January 1, 1992, there shall be a health professional certified in advanced pediatric life support available within the unit at all times.

8:43G-22.16 Pediatric intensive care staff time and availability

(a) There shall be a physician who can handle pediatric emergencies, other than the physician assigned to the emergency department, in the hospital at all times.

(b) There shall be at least one registered professional nurse to every two patients in the pediatric intensive care unit.

(c) There shall be at least one full-time clerical support staff person assigned full or part time to the pediatric intensive care unit.

(d) The services of the following staff with specialized training or experience in pediatrics shall be available to pediatric intensive care unit patients and their families: child-life specialist, social worker, physical therapist, occupational therapist, psychiatrist, and nutritionist.

(e) The hospital shall have available a transport team staffed by health professionals with special training in pediatrics.

8:43G-22.17 Pediatric intensive care patient services

(a) The following services shall be available to the pediatric intensive care unit at all times:

1. Blood bank;
2. Dialysis;
3. Hematology;
4. Laboratory;
5. Nuclear medicine;
6. Pharmacy;
7. Radiology;
8. Computer tomography; and
9. Respiratory therapy.

(b) There shall be a system that is available to the pediatric intensive care unit at all times for transporting acutely ill children between hospitals.

(c) There shall be a policy that addresses optional overnight stays in the hospital or adjacent buildings for parents or guardians of pediatric intensive care patients.

8:43G-22.18 (Reserved)

8:43G-22.19 Pediatric intensive care space and environment

(a) There shall be at least one isolation room in the pediatric intensive care unit. There shall be additional isolation rooms based on a ratio of one room to every six pediatric intensive care beds.

(b) The pediatric intensive care unit shall be a closed unit, and no traffic to other departments or units shall pass through it.

(c) There shall be a room nearby the pediatric intensive care unit where the physician can sleep.

(d) There shall be a sitting room or lounge area nearby the pediatric intensive care unit for the families of patients in the unit.

8:43G-22.20 Pediatric intensive care supplies and equipment

(a) The pediatric intensive care unit shall have immediate access to equipment that has the capability for continuous monitoring of at least:

1. Arterial pressure;
2. Central venous pressure;
3. Electrocardiogram;
4. Heart rate;
5. Intracranial pressure;
6. Pulmonary arterial pressure;
7. Respiration;
8. Temperature; and
9. Three simultaneous pressure capability.

(b) The pediatric intensive care unit shall have immediate access to the following equipment:

1. Defibrillator;
2. Intravenous fluid warmer;
3. Metabolic bed scale; and
4. Pulse oximeter.

(c) The pediatric intensive care unit shall have access to the following equipment within the hospital:

1. Bilirubin lights;

2. End tidal carbon dioxide measurement; and

3. Isolation equipment.

(d) Provisions shall be available for emergency repair of biomedical equipment in the pediatric intensive care unit.

8:43G-22.21 (Reserved)

8:43G-22.22 Pediatric intensive care continuous quality improvement methods

The continuous quality improvement program for pediatric intensive care shall include interhospital exchanges or information and case reviews with pediatric specialists in other hospitals.

SUBCHAPTER 22A. LICENSURE OF CHILDREN'S HOSPITAL DESIGNATION

8:43G-22A.1 Scope of children's hospital designation standards

The standards set forth in this subchapter shall apply only to hospitals that are licensed as children's hospitals.

8:43G-22A.2 Organizational structure

(a) The hospital shall have a governing body, which shall carry out the following responsibilities: safeguard the program's resources; approve the children's program's long range plan; and, approve the children's program's operation plans. The governing body shall meet either of the following criteria:

l. Constitute a separate, autonomous governing body of either a subsidiary corporation or multi-hospital system; or

2. Constitute a standing committee of the governing body charged with ongoing children's program review, together with a dedicated fundraising program for the children's hospital, which reports periodically to the standing committee.

(b) There shall be an individual responsible for the administration of the children's program and for patient care services, particularly for the coordination and direction of nursing services, who shall be accountable to the standing committee of the governing body.

(c) The children's program shall have fiscal autonomy which shall conform with either of the following:

1. A separate Medicare provider number;

2. A separate operating budget, with separate control over income and expenses; or

3. Defined costs for the children's program, with

i. Discrete cost centers which allocate the cost of all services provided, including, but not limited to, overhead, indirect costs; and

ii. A separate staffing plan.

8:43G-22A.3 Continuous quality improvement

The hospital shall have an organized quality improvement program for each pediatric service 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. The data shall include, but not be limited to, the number of child admissions.

8:43G-22A.4 Medical staff and teaching program

(a) The hospital shall be a teaching site for an organized academic department of pediatrics of an approved medical school program.

(b) The hospital shall be engaged in an ongoing clinical research program.

(c) The pediatric teaching program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education (ACGME) or any other group approved by the State Board of Medical Examiners for a minimum of 12 pediatric resident positions.

8:43G-22A.5 Building and facilities

(a) The children's program shall have adequate physical space and facilities provided either in a separate building(s) or in a defined and contiguous space within a building reserved for the housing of children which shall include:

1. Inpatient facilities separate from obstetrics:

2. Organized and accessible outpatient clinics for children that shall have, at a minimum, space reserved for children at scheduled times; and

3. A discrete pediatric area within the emergency department within by October 21, 2005.

8:43G-22A.6 Essential special care services

(a) By October 21, 2003, all licensed children's hospitals shall operate a pediatric intensive care unit in accordance with N.J.A.C. 8:43G-22.

(b) A licensed children's hospital not licensed to operate a pediatric intensive care unit on October 21, 2002 rules shall file a licensing application to initiate such a unit in accordance with (a) above. Such a licensing application shall be filed in accordance with the procedures described in N.J.A.C. 8:43G-2.2 through 2.5, as
applicable.

(c) By October 21, 2003, all licensed children's hospitals shall operate a regional perinatal center in accordance with N.J.A.C. 8:43G-19, and applicable provisions of N.J.A.C. 8:33C, including 8:33C-3.4(a)3 through 10.

(d) A licensed children's hospital not licensed to operate a regional Perinatal center on October 21, 2002 shall file a licensing application to initiate such a service, including neonatal intermediate and intensive care unit(s), in conformance with (c) above. Such a licensing application shall be filed in accordance with the procedures described in N.J.A.C. 8:43G-2.2 through 2.5, as applicable.

(e) A licensed children's hospital not also licensed to operate a pediatric intensive care unit or a regional perinatal center on October 21, 2002 shall not be required to obtain certificate of need approval to establish such a unit or center, including neonatal intensive or intermediate care unit(s) within the center.

1. A licensed children's hospital without a licensed pediatric intensive care unit may establish such a unit with a maximum size of six beds without certificate of need approval.

2. A licensed children's hospital without a licensed neonatal intermediate or intensive care unit may establish such a unit(s) with a maximum size of four bassinets for an intermediate care nursery and six bassinets for an intensive care nursery without certificate of need approval.

SUBCHAPTER 23. PHARMACY

8:43G-23.1 Pharmacy structural organization

(a) A hospital shall have a pharmacy that is licensed by the New Jersey State Board of Pharmacy, with a current Drug Enforcement Administration registration and a controlled dangerous substance registration from the State Department of Health.

(b) A multidisciplinary pharmacy and therapeutics committee, or an equivalent multidisciplinary body which includes a pharmacist licensed to practice pharmacy in New Jersey, shall meet at least quarterly and document its activities, findings, and recommendations.

8:43G-23.2 Pharmacy policies and procedures

(a) The pharmacy and therapeutics committee, or its equivalent, shall review, approve, and ensure implementation of policies and procedures addressing at least the following areas:

1. Outpatient pharmacy services;

2. Administration of drugs;

3. Use of patients' previously acquired drugs, including requirement for physician orders and pharmacy identification of the drugs before use;

4. Admixture of intravenous solutions, including quality control and safety procedures for laminar airflow hoods and labeling;

5. Storage and distribution of drugs, including at least dispensing devices (if used in the hospital), emergency drugs and kits, and control and accountability of controlled substances in accordance with applicable laws and regulations;

6. Stop orders and discontinue orders, including the length of time all orders stay in effect, stoppage of drugs on the day a patient undergoes surgery in conformance with the prescriber's specifications, and notification of the prescriber of the expiration of a drug order;

7. Identification, reporting, reviewing, and monitoring of adverse drug reactions and medication errors;

8. Identification and prevention of food/drug interactions and responsibility of pharmacy, nursing, and dietary services, including responsibility for the following:

i. Ensuring that appropriate food or fluid requirements are met when administering medication;

ii. Adjusting the contents of the patient's meal tray whenever an increase or decrease in a specific nutrient is ordered; and

iii. Educating the patient about potential food/drug interactions prior to discharge and

9. Current reference materials kept at drug distribution stations and in the pharmacy, and made available to medical and nursing staff;

10. Control and limitation of use of drugs marked "sample";

11. Approval and maintenance of an up-to-date formulary;

12. Pharmacists' clarifications of physician orders; and

13. Self-administration of drugs, if permitted by the hospital, including a requirement for written prescriber orders, storage of drugs, labeling of drugs, documentation of self-administration in the patient medical record, patient training and education, and precautions to ensure that a patient does not take the drugs of another patient.

8:43G-23.3 Pharmacy staff qualifications

(a) Pharmaceutical services shall be directed by a registered pharmacist licensed to practice pharmacy in New Jersey.

(b) A pharmacist licensed to practice pharmacy in New Jersey shall be responsible for compounding, preparing, labeling, transferring between containers, and dispensing drugs, including direct supervision of supportive personnel, as defined at N.J.A.C. 13:39-1.2.

8:43G-23.4 Pharmacy staff time and availability

(a) A pharmacist licensed to practice pharmacy in New Jersey shall be on duty or on call at all times.

(b) When, in the pharmacist's absence from the hospital, a registered professional nurse removes a drug from the designated pharmacy stock or night cabinet for use in an emergency, this action shall be recorded by the nurse and checked by a pharmacist on a daily basis.

(c) If the hospital operates a decentralized pharmaceutical service, there shall be a pharmacist licensed to practice pharmacy in New Jersey assigned to each satellite pharmacy during the satellite pharmacy's hours of operation.

8:43G-23.5 (Reserved)

8:43G-23.6 Pharmacy patient services

(a) Pharmaceutical services shall be available to patients at all times.

(b) The hospital shall have in effect a unit dose drug distribution system with individual cassettes or containers which bear the patient's identification. The system shall cover at least the medical/surgical, obstetric, pediatric, and psychiatric units and include scheduled cart exchanges at least every 24 hours, including weekends and holidays.

1. An alternative method of distributing drugs approved by the Department of Health may be substituted for the unit dose drug distribution system if the method has been demonstrated to the Department to have at least equivalent clinical effectiveness.

(c) The dispensing of fractional and multiple dosages shall be at the discretion of the pharmacy and therapeutics committee or its equivalent, provided cautionary instructions and ancillary information about these dosages are communicated to the personnel responsible for administering them.

(d) The pharmacy service shall develop and implement a system of control for legend drug doses. A pharmacist licensed to practice pharmacy in New Jersey shall check each cassette or container of drugs prepared by supportive personnel, as defined at N.J.A.C. 13:39-1.2, before it is delivered to a patient care unit.

(e) The hospital shall have a pharmacy-based intravenous infusion admixture program, which includes services related to preparation of total parenteral nutrition, antineoplastic agents, and large and small, continuous or intermittent volume products for infusion. A pharmacist licensed to practice pharmacy in New Jersey, or supportive personnel, as defined at N.J.A.C. 13:39-1.2, shall prepare, sterilize if necessary, and label parenteral medications and solutions, except in those areas or situations that have been excluded by the pharmacy and therapeutics committee or its equivalent.

(f) Cautionary instructions and ancillary information about medications shall be communicated in writing to the personnel responsible for administering medications.

(g) All medication orders shall specify the name of the drug, dose, frequency, and route of administration, and shall be dated and signed (or approved by authorization code if ordered through computer entry) by the prescriber.

(h) Allergies, including allergy to latex, shall be documented in the patient's pharmacy profile.

(i) Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source and exact identification (such as lot number), and outdated medications shall be returned to the pharmacy for disposal.

(j) Initials or identifying codes shall be used by pharmacy personnel, and a list of these initials or codes and the corresponding printed or typed names and signatures shall be kept for at least five years after termination of pharmacy service employment.

(k) Current antidote information shall be provided in the pharmacy. The telephone number of the designated Statewide or regional New Jersey Poison Information and Education System (1-800-962-1253) shall be provided in the pharmacy and in each patient care unit or area.

(l) Current Federal and State drug law information shall be available to the pharmacy service.

(m) Drug product defects shall be reported in accordance with the drug product problem reporting system of the United States Pharmacopoeia or of the Food and Drug Administration.

8:43G-23.7 (Reserved)

8:43G-23.8 Pharmacy space and environment

(a) The pharmacy shall maintain drugs under proper conditions, as indicated in the United States Pharmacopoeia, product labeling, and/or package inserts.

(b) All drugs, needles, and syringes shall be kept in locked storage areas except those drugs exempted by the pharmacy and therapeutics committee or its equivalent under specified conditions.

8:43G-23.9 Pharmacy staff education and training

Requirements for the pharmacy education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-23.10 Pharmacy continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for the pharmacy service that is integrated into the hospital continuous quality improvement program and 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.

(b) The pharmacy service shall have in effect a patient profile system for monitoring drug therapy. This system shall be used by the hospital to identify inappropriate prescribing practices.

(c) The pharmacy service shall inspect at least once every two months all patient care areas in the hospital, and at least once every three months all other areas of the hospital where drugs intended for administration to patients are dispensed, administered, or stored. The pharmacy service shall maintain a record of the inspections. Identified problems shall be addressed.

(d) A quality improvement program of the pharmacy service shall monitor, at a minimum, the use of drugs, including medication errors and use of antibiotics. Serious or consistent patterns of medication error shall be reported to the pharmacy and therapeutics committee or its equivalent.

8:43G-23.11 (Reserved)

SUBCHAPTER 24. PLANT MAINTENANCE AND FIRE AND EMERGENCY PREPAREDNESS

8:43G-24.1 Plant maintenance structural organization

(a) There shall be a multidisciplinary safety committee that develops a comprehensive hospital-wide safety program that is reviewed at least once every three years, revised more frequently as needed, and implemented.

(b) There shall be a mechanism to report all incidents, injuries and safety hazards to the safety committee.

(c) The safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.

8:43G-24.2 Plant maintenance policies and procedures

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

(b) The building maintenance service shall have a written preventive maintenance program for buildings, equipment and utilities.

8:43G-24.3 Plant maintenance staff qualifications

(a) The building maintenance service shall be under the supervision of an employee with at least one of the following qualifications:

1. Five years of experience in health care plant maintenance, three of which shall be in a supervisory capacity;

2. A baccalaureate degree in engineering from an accredited college or university and three years of experience in health care plant maintenance, two of which shall be in a supervisory capacity; or

3. A current professional engineer license in New Jersey and three years of experience in health care plant maintenance, two of which shall be in a supervisory capacity.

(b) There shall be an in-hospital or contracted biomedical electronics equipment maintenance and safety program under the supervision of an individual with at least:

1. A two-year associate's degree in biomedical engineering from an accredited college or university and two years of experience in the field of biomedical engineering; or

2. Four years of combined experience and/or training from an accredited technical school or military program.

8:43G-24.4 Plant maintenance services

(a) Records of preventive maintenance inspections and repairs of electrical and mechanical systems shall be maintained for at least one year.

(b) The building maintenance service shall be provided with copies of the written instructions for operating and maintaining departmental and unit equipment. These instructions shall be systematically retained in the departments or units in which the equipment is used.

(c) All life-sustaining equipment shall be plugged into outlets connected to the emergency power supply.

(d) Routine maintenance inspections of elevators shall be conducted in accordance with local ordinances.

(e) The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.

(f) Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.

8:43G-24.5 (Reserved)

8:43G-24.6 Plant maintenance staff education

Requirements for the plant maintenance education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-24.7 (Reserved)

8:43G-24.8 Physical plant general compliance for new construction, alteration or renovation

(a) The hospital shall comply with the New Jersey Uniform Construction Code (N.J.A.C. 5:23 under Use Group I-2), standards imposed by the United States Department of Health and Human Services (HHS), the New Jersey Departments of Health and Senior Services and Community Affairs, and the Guidelines for Design and Construction of Hospital and Healthcare Facilities (2001 edition, as published by The American Institute of Architects Press, 1735 New York Ave., NW, Washington, D.C. 20006, Pub. No. ISBN 1-57165-992-04, as amended and supplemented, incorporated herein by reference. In order to avoid conflict between N.J.A.C. 5:23 and the other standards listed above, Sections 501.3, 610.4.1, 704.0, 705.0, 706.0, 708.0, and 916.5 of the 1987 BOCA Basic Building Code of the New Jersey Uniform Construction Code shall not govern with respect to health care facilities.

(b) The hospital shall submit plans and specifications to Health Plan Review, Division of Codes and Standards, Department of Community Affairs, P.O. Box 815, Trenton, N.J. 08625-0815, for approval prior to construction, alteration, or renovation.

8:43G-24.9 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.

8:43G-24.10 (Reserved)

8:43G-24.11 (Reserved)

8:43G-24.12 (Reserved)

8:43G-24.13 Fire and emergency preparedness

(a) The hospital shall comply with the 1985 edition of the National Fire Protection Association "Life Safety Code" (N.F.P.A. 101, Chapter 12 for new construction and Chapter 13 for existing construction), available from NFPA, 1 Batterymarch Park, Quincy, MA, 02169, (1-800-344-3555). If the building was constructed prior to 1968, the hospital shall have the option of applying for approval from the State Department of Health under Fire Safety Evaluation System (FSES) requirements. Such approval shall be obtained prior to the annual licensure inspection survey and shall include prearranged inspection by a State Department of Health surveyor.

(b) All employees, including part-time employees, temporary agency personnel, and private duty nurses 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 of hospital buildings as part of their initial orientation and at least annually thereafter.

(c) All employees, including part-time employees, temporary agency personnel, and private-duty nurses, shall receive printed instructions on procedures to be followed in case of emergency, including patient evacuation of the buildings.

(d) A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall in each patient care unit.

(e) Exits, stairways, doors, and corridors shall be kept free of obstructions.

(f) Fire drills shall be conducted at least 12 times per year, with at least one drill on each shift and one drill on a weekend.

(g) Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydrotested as required by manufacturer's instructions; and labeled with the date of the last inspection.

(h) Fire detectors and alarm systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.

(i) Fire suppression systems shall be tested at least twice a year by an approved and certified testing agency. Written reports of the last two inspections shall be kept on file.

(j) There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.

(k) There shall be a procedure for investigating and reporting fires. All fires that result in a patient or patients being moved shall be reported to the New Jersey State Department of Health immediately by telephone at (609) 588-7725 or (609) 392-2020 after business hours and followed up in writing within72 hours. In addition, a written report of the investigation shall be forwarded to the Department of Health as soon as it becomes available.

(l) The hospital shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough stored fuel to maintain power for at least 24 hours.

8:43G-24.14 (Reserved)

SUBCHAPTER 25. POST MORTEM

8:43G-25.1 Policies and procedures

(a) The hospital shall have written policies and procedures for post mortem services that are reviewed at least once every three years, revised more frequently as needed, and implemented. These policies shall delineate the responsibilities of the medical staff, nursing, and post mortem services staff, and shall include procedures for at least the following:

1. Identifying the body;

2. Safe and proper handling to prevent damage to the body;

3. Safeguarding personal effects of the deceased and release of personal effects to the appropriate individual;

4. Handling of toxic chemicals by morgue and housekeeping staff;

5. Infection control, including disinfection of equipment;

6. Identifying and handling high-risk and/or infectious bodies, in accordance with Centers for Disease Control guidelines, and in compliance with N.J.S.A. 26:6-8;

7. Release of the body to the county morgue or funeral director;

8. Autopsy requests;

9. Availability of autopsy reports, including reports of microscopic autopsy findings, to physicians and in medical records, within specified time frames; and

10. Completion of autopsy, including microscopic and other procedures, within specified time frames.

8:43G-25.2 Post mortem staff qualifications

The physician who routinely performs or supervises the performance of autopsies shall be Board Certified in Pathology.

8:43G-25.3 Post mortem patient services

(a) Bodies and body parts in the morgue shall be kept refrigerated or in chemical fixation in a non-putrescent state.

(b) The medical staff shall attempt to secure autopsies in cases of unusual deaths, deaths from unknown causes, and cases of medicolegal and educational interest, unless otherwise provided for by law.

(c) Autopsies shall be performed only with the consent of the patient's family or guardian in accordance with N.J.S.A. 26:6-50. Consent shall not be required for medical examiner cases.

(d) The hospital shall notify the county medical examiner or prosecutor immediately upon a patient's death when the circumstances of the death fall within the criteria specified in N.J.S.A. 52:17B-86 of the State Medical Examiners Act, N.J.S.A. 52:17B-78 et seq.

8:43G-25.4 Post mortem space and environment

The morgue shall be equipped with refrigerated space to store at least two bodies. Hospitals with more than 100 beds shall provide additional space using a ratio of one space to every additional 100 beds.

8:43G-25.5 Post mortem supplies and equipment

Refrigerated spaces in the morgue shall be maintained at temperatures between 32 and 45 degrees Fahrenheit (0 and 7.2 degrees Celsius) and shall have an automatic alarm system that monitors the temperature.

SUBCHAPTER 26. PSYCHIATRY

8:43G-26.1 Scope of psychiatry standards

The standards in this subchapter shall apply only to hospitals that have a separate, designated unit or service for psychiatry.

8:43G-26.2 Psychiatry policies and procedures

(a) The psychiatric service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies and procedures shall be readily available on the inpatient unit and include at least the following:

1. Criteria for admission to and discharge from each component of the psychiatric unit. Admissions criteria shall be based solely on the patient's needs and the ability of the unit to meet these needs, and discharge policies shall preclude punitive discharge;

2. Safety and security precautions for the prevention of suicide, assault, elopement, and patient injury;

3. Emergency procedures for medical emergencies;

4. Infection control practices for the day/dining room, equipment, and rooms used by more than one patient. If these special practices are included in the hospital-wide infection control policies and procedures manual, which is available on the unit, then additional policies and procedures do not have to be developed by the psychiatric service for infection control;

5. Patient privileges;

6. Patient rights as delineated at N.J.A.C. 8:43G-4;

7. Family interviews for assessment and treatment purposes;

8. A clinical services plan describing the services provided;

9. Content of patient evaluations, including the components of care, time frames for goals, and staff assigned to the patient;

10. Release of information, in conformance with applicable statutes and the policies of the medical records department;

11. Informed consent, with special policies for patients undergoing electro-convulsive therapy;

12. Patient grievance procedures;

13. Criteria for use of seclusion in accordance with procedures delineated in the current or revised or later edition, if in effect, of the American Psychiatric Association Task Force Report No. 22 on Restraint and Seclusion, incorporated herein by reference, available from the American Psychiatric Association, 1400 K Street NW, Washington, D.C. 20005;

14. Review by physician director or designee of restraints or seclusion used in excess of 72 consecutive hours for a patient; and

15. Criteria for physician monitoring of patients in restraints more frequently than every 24 hours based on patient acuity.

(b) The psychiatric service shall develop and implement written policies and procedures for use of restraints in accordance with N.J.A.C. 8:43G-18.4.

(c) The psychiatric service shall develop and implement written policies and procedures for use of electroconvulsive therapy (ECT), in accordance with the recommendations of the current or revised or later edition, if in effect, of the American Psychiatric Task Force on ECT: "The Practice of ECT: Recommendations for Treatment, Training, and Privileging" and the New Jersey Patient's Bill of Rights at N.J.S.A. 30:4-24.2(d)(2), incorporated herein by reference, including at least:

1. Criteria specifying when ECT may be used;

2. The use of written informed consent;

3. The requirement that an anesthesiologist, a certified registered nurse anesthetist, or a physician granted privileges by the medical staff to administer anesthesia be present at the procedure;

4. Administration in an appropriately equipped area, with emergency equipment available;

5. Full documentation of the administration of ECT in the medical record; and

6. Observation of the patient's recovery immediately after the procedure is performed.

(d) There shall be a written affiliation or referral agreement with the community mental health agency or agencies designated within the hospital's service area by the New Jersey Division of Mental Health and Hospitals for referral, case management, and discharge planning.

(e) The hospital shall comply with the provisions of the New Jersey Screening and Commitment Law of 1988, N.J.S.A. 30:4-27.1 et seq., specifically N.J.S.A. 30:4-27.10(f), and all rules promulgated pursuant to the aforementioned Act in regards to the transfer of a patient to a psychiatric facility.

8:43G-26.3 Psychiatry staff qualifications

(a) Psychiatric care services shall be clinically supervised by a physician director who is responsible for the direction and quality of care provided by the medical staff.

(b) Any physician currently holding the position of director shall have completed a residence in psychiatry or neurology and shall be able to demonstrate the skills and experience at least equivalent to certification by the American Board of Psychiatry and Neurology. Effective July 1, 1990 any newly appointed physician director shall be board certified or shall meet the training and experience requirements for examination by the Board and shall be examined within two years of eligibility.

(c) Nursing on the psychiatric care unit shall be directed by a registered professional nurse with at least three years of clinical psychiatric experience.

(d) The social worker assigned to the inpatient psychiatric unit shall have at least a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education, or a bachelor's degree from an accredited social work program and one year of experience in social work or mental health.

8:43G-26.4 (Reserved)

8:43G-26.5 Psychiatry staff time and availability

(a) A psychiatrist shall be on-site or on call at all times.

(b) Nurse staffing shall be based on hospital acuity levels, but in no case shall fewer than two nursing staff members, at least one of whom is a registered professional nurse, be on the unit.

8:43G-26.6 (Reserved)

8:43G-26.7 Psychiatry patient services

(a) Psychiatric patients shall receive, when needed, all medical, surgical, diagnostic, and treatment services as ordered by a physician. If such services are not available within the hospital, qualified consultants and attending physicians shall be available and arrangements established for transferring patients to a facility where the needed services can be provided.

(b) All patients shall receive a complete history and physical examination by a physician, advanced practice nurse or physician assistant within 24 hours of admission to the psychiatric unit.

(c) The following services shall be available as part of the program of the psychiatric care unit:

1. Individual, group, and family therapy;

2. Psychotropic medications;

3. Rehabilitative services;

4. Psychological services, including testing, provided by a psychologist licensed by the State of New Jersey; and

5. Recreational therapy.

(d) A social worker shall complete a psychosocial assessment for each patient which includes at least:

1. Identified problems;

2. Social and family history;

3. Educational and employment history;

4. Financial status; and

5. Present living arrangements.

(e) A written psychiatric evaluation shall be performed of each patient by a psychiatrist, advanced practice nurse or physician assistant within 24 hours of admission to the unit.

(f) The psychiatric evaluation shall be documented in the medical record and shall include at least:

1. The chief complaint;

2. A history of present illness;

3. A family history;

4. A pertinent medical history, including previous reactions to psychotropic medications;

5. A mental status; and

6. A diagnostic impression.

(g) An individual, comprehensive, multidisciplinary care plan shall be developed for each patient based on an assessment of the patient's strengths and limitations. The written care plan shall include at least:

1. A psychiatric diagnosis specifying intercurrent diseases;

2. Observable treatment goals;

3. The specific treatment methods to be used; and

4. The responsibilities of each member of the interdisciplinary care team.

(h) The multidisciplinary care plan shall be discussed with the patient and implemented.

(i) Each patient's plan of care shall be formulated in a multidisciplinary conference, which includes members of all disciplines involved in treating the patient.

(j) The multidisciplinary plan of care shall be reassessed at least weekly by all members of the professional team who are involved in the patient's care.

(k) If the patient is admitted to the psychiatric unit through the emergency department and the patient gives consent, the patient's primary-care physician shall be contacted in order to inform the physician about the patient's condition and to obtain information about the patient's medical status.

(l) Written discharge plans shall be developed for each patient by members of a multidisciplinary team, who either meet or make notes individually in the patient's record.

(m) There shall be mechanisms for providing immediate security assistance to staff and patients.

(n) Patients shall be advised of the reasons for, and expected effects of, medications prescribed for them.

(o) There shall be a milieu program that includes patient community meetings and daily activities.

(p) An accurate schedule of activities shall be posted conspicuously in the unit.

8:43G-26.8 (Reserved)

8:43G-26.9 Psychiatry space and environment

(a) Interviews between staff and patients shall be conducted in a private setting.

(b) The unit shall have access to at least one acute care/seclusion room.

(c) Acute care/seclusion rooms shall beat least 100 square feet and shall be large enough to provide access to the patient from all sides of the bed or mattress and have room for emergency life-sustaining equipment.

(d) Patients in acute care/seclusion rooms shall be either under direct observation in a room near the nurses station or observed through the use of electronic monitoring equipment.

(e) The unit shall have a day room/dining room that allows for social interaction, dining, and therapy.

(f) Opportunities to participate in structured physical exercise programs shall be made available to patients.

(g) There shall be space in each patient room for storage of patients' personal belongings. There shall be a system for securing patients' valuable belongings.

(h) The psychiatric care unit shall comply with the suicide prevention regulations as provided in Federal Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1987 Edition, section 7.6, or later edition, if in effect, which are hereby incorporated by reference, and are available from The American Institute of Architects Press, 1735 New York Ave. NW, Washington, D.C. 20006, Pub. No. ISBN 0-913962-96-1.

(i) Authorized security personnel shall have immediate access to locked units.

(j) There shall be a system for summoning help from other areas of the unit in an emergency.

8:43G-26.10 (Reserved)

8:43G-26.11 Psychiatry supplies and equipment

(a) The restraint equipment needed by the unit shall be immediately available on the unit and accessible to unit staff.

(b) The recreation and therapy equipment and supplies needed for psychiatric care shall be available on the unit and stored in locked storage.

(c) Locked storage areas shall be available for supplies and the safekeeping of the individual, ongoing creative projects of patients.

8:43G-26.12 Psychiatry staff education

(a) Requirements for the psychiatry service education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) The staff of the psychiatric unit shall receive annual training in handling the assaultive patient.

(c) The non-medical and non-nursing professional staff shall receive annual training in drug effects and side effects.

8:43G-26.13 (Reserved)

8:43G-26.14 Psychiatry quality assurance methods

(a) There shall be a program of quality assurance for psychiatric services that is integrated into the hospital quality assurance program and 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.

(b) The ongoing quality assurance program of the psychiatric service shall include incident review and monitoring of such areas as suicide, attempted suicide, elopement, assaults, slips and falls, patient abuse and neglect, use of seclusion, and use of restraints.

(c) The medical staff shall review, on at least an annual basis, use of restraints, discharge planning, and outcomes.

8:43G-27.5 Continuous quality improvement patient services

(a) There shall be an ongoing process of monitoring patient care. Evaluation of patient care throughout the hospital is criteria-based, so that certain review actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

(b) The continuous quality improvement coordinator shall be available to provide ongoing consultation to each department including assistance with the development of specific indicators used to evaluate service outcome in each department.

(c) The program shall follow up on its findings to assure 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.

(d) The continuous quality improvement program shall identify and establish indicators of quality care specific to the hospital that are monitored and evaluated and encompass at least:

1. Surgical case review;

2. Drug usage;

3. Medical record review;

4. Blood usage;

5. Pharmacy and therapeutics function; and

6. Appropriateness of specific diagnostic and therapeutic procedures, as selected by the continuous quality improvement program.

(e) The continuous quality improvement program shall provide information that is utilized in the evaluation of the clinical competence of all clinical practitioners.

8:43G-27.6 Performance measurement and assessment system

(a) The Department shall establish a Quality Improvement Advisory Committee (QIAC), including provider, consumer and individuals with quality of care research expertise representation, to advise the Department in developing a hospital performance measurement and assessment system. The data collected through this system shall be used by the Department to:

1. Promote the standardized reporting of data by hospitals;

2. Provide the Department with information on the performance of hospitals to support the Department's oversight role;

3. Assist general hospitals to measure and improve the quality of care provided within their facilities;

4. Support efforts to inform consumers about performance of individual hospitals and the industry as a whole; and/or

5. Any other purpose consistent with this chapter, particularly N.J.A.C. 8:43G-17.

(b) The Quality Improvement Advisory Committee shall advise the Department on the development of a uniform data reporting system to obtain reliable, standardized and comparable information from all hospitals. This quality performance measurement reporting system may include measures of:

1. Processes of care demonstrated to significantly enhance patient outcomes;

2. Patient outcomes, risk-adjusted where feasible and appropriate;

3. Patient satisfaction with the care provided; and

4. Other indicators of care as recommended by the QIAC.

(c) To minimize costs to hospitals and the Department, performance measures shall incorporate, when possible, data routinely collected by hospitals or available to the Department from other sources. Data for this quality performance measurement system may be derived from, but not be limited to, the following:

1. Medical record chart review;

2. Patient satisfaction surveys;

3. Computerized health care encounter data; and

4. Administrative data systems including billing data.

(d) Where applicable, the Department shall use nationally recognized performance measurements/indicators to promote cost-effective collection and reporting of data.

(e) Hospitals shall submit quality performance measurement data as the Department shall request from time to time directly from each hospital.

(f) The Department may conduct audits of each hospital's performance measurement indicator data including on-site audits, where applicable.

(g) During the development and implementation of the uniform data reporting system, the QIAC shall address the following:

1. The relevance, validity and reliability of each measure selected to be an indicator of performance;

2. Methods for improving the quality of care in hospitals;

3. Protection of confidentiality of patient-specific information;

4. Cost and difficulty of data collection;

5. Measures to reduce duplicative reporting of information;

6. Public release of data in formats useful to purchasers and/or consumers; and

7. Methods for efficient utilization of resources.

(h) The QIAC shall meet on an ongoing basis to evaluate data as it is received by the Department, and shall advise the Department on processes for disseminating analyses of data collected in order to promote improved performance.

SUBCHAPTER 28. RADIOLOGY AND RADIATION ONCOLOGY

8:43G-28.1 Radiology structural organization

Radiological services shall be provided on-site, except for specialized services that have been approved through the Certificate of Need process to be provided on an off-site regional basis.

8:43G-28.2 Radiology policies and procedures

(a) The radiology 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, including patients in isolation.

(b) The radiology service's policies and procedures manual shall be available to staff in the radiology unit.

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

8:43G-28.3 (Reserved)

8:43G-28.4 (Reserved)

8:43G-28.5 Radiology continuous quality improvement methods

There shall be a program of continuous quality improvement for the radiology service that is integrated into the hospital continuous quality improvement program and 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.

8:43G-28.6 (Reserved)

8:43G-28.7 Diagnostic services staff qualifications

All radiologists performing diagnostic radiology services in the hospital shall have successfully completed an approved graduate medical education residency training program in radiology.

8:43G-28.8 Diagnostic services staff time and availability

(a) A radiologist who has completed a residency training program in radiology shall be able to arrive, and shall arrive, at the hospital within 30 minutes of being summoned, under normal transportation conditions.

(b) A currently licensed radiologic technologist shall be present in the hospital or on call at all times; if on call, the technologist shall be able to arrive, and shall arrive, at the hospital within 30 minutes of being summoned, under normal transportation conditions.

(c) A registered professional nurse shall be available in the radiology service when needed, in the physician's judgment, to administer medications and perform other nursing duties.

8:43G-28.9 (Reserved)

8:43G-28.10 Diagnostic services patient services

(a) Radiologists shall supervise and interpret all radiologic procedures, unless performed by clinical practitioners in specialty areas who are trained and experienced in these procedures.

(b) All radiologic tests shall be interpreted, on a preliminary basis, within 24 hours of the time that test results are available for interpretation.

(c) If provided by the hospital, computer tomography shall be available within one hour at all times, when deemed appropriate in the judgement of the radiologist, unless the machinery is temporarily disabled or in use.

(d) Ultrasound shall be available within one hour at all times, unless the machinery is temporarily disabled or in use.

(e) If provided by the hospital, nuclear medicine shall be available within one hour at all times, unless the machinery is temporarily disabled or in use, or unless the needed pharmaceutical product is unavailable.

(f) If provided by the hospital, special procedures such as angiography and interventional procedures shall be available within one hour at all times, when deemed appropriate in the judgement of the radiologist, unless the machinery is temporarily disabled or in use.

(g) The radiology staff shall make every effort to ensure that patients waiting for radiology services or transport from radiology are comfortable while waiting and that the service responsible for transporting the patient back to the unit is notified when the patient is ready to be returned.

(h) Fluoroscopy with image intensification and a general radiographic room, and a mobile x-ray unit, shall be available.

8:43G-28.11 (Reserved)

8:43G-28.12 Diagnostic services supplies and equipment

(a) Cardiopulmonary resuscitation technology shall be immediately available to radiology services on all shifts. This technology shall include at least:

1. A patient monitor and defibrillator;

2. Emergency drugs; and

3. Means of maintaining respiration.

8:43G-28.13 Radiation 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.

1. For the purpose of this rule a qualified radiation oncologist shall be:

i. Certified by the American Board of Radiology in general radiology, radiation oncology or therapeutic radiology prior to 1976; or

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

2. 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.

3. Upon application made to the Department by the physician, a waiver of board certification requirement may be granted to a radiation oncologist who is licensed by and in good standing with the New Jersey Board of Medical Examiners as of December 20, 1999. If granted, the waiver shall remain for the duration of the applicant's career unless the applicant fails to maintain his or her status of good standing with the New Jersey Board of Medical Examiners. Should the applicant fall out of good standing with that Board, the waiver shall automatically become null and void. Physicians falling out of good standing, and subsequently achieving good standing status, shall be eligible to reapply for a subsequent waiver, provided the applicant shall show cause why a subsequent waiver should be approved.

(b) All radiation therapists in the radiation oncology service 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.

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

1. For the purposes of this regulation, qualified radiological physicist shall mean one who:

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

ii. Any individual who does not meet the criteria in (c)1i above, but who meets the qualifications specified in N.J.A.C. 7:28-14.2, "Qualified radiological physicist," may petition the Commission of Radiation Protection for recognition as a "qualified radiologist physicist." The individual shall submit a written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified radiological physicist.

8:43G-28.14 Radiation oncology services staff time and availability

(a) During regular hours, a radiation oncologist shall be physically on site when patients are receiving radiation treatments, except for routine absences of a short duration (such as during a lunch break, local tumor board meeting, or institutional committee meeting) or for brief unexpected absences. Such absences shall not constitute more than 10 percent of the time that patients are under treatment. On site shall include the radiation oncology facility or radiation oncology facility campus.

(b) After the radiation oncology facility is closed a radiation oncologist shall be available for telephone consultation within one hour of being summoned and be 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 (therapy technologist) therapist or radiation oncologist present to operate each cobalt machine when it is in use.

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

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

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

(g) A professional member of the social work department shall be available on a full or part-time basis to the radiation oncology unit to meet the psychosocial needs of radiation oncology patients and families.

8:43G-28.15 (Reserved)

8:43G-28.16 Radiation oncology patient services

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

(b) Individual patient records of radiation oncology treatments 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.

8:43G-28.17 (Reserved)

8:43G-28.18 Radiation oncology services supplies and equipment

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

(b) Emergency drugs shall be immediately available to the radiation oncology service.

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

(d) All new single unit facilities shall have dual photon energy equipment with electron capability. All existing single unit facilities shall obtain dual photon energy equipment with electron capability by December 20, 2002.

(e) By December 20, 2002, new or replacement machines shall, at a minimum, provider greater than or equal to 10 MV photon energy level capability and greater than or equal to 10 MeV electron energy level capability unless another machine already exists at that facility with these capabilities.

(f) By December 20, 2002, all cobalt 60 machines shall be replaced with machines meeting the specifications outlined in sections (d) and (e) above.

8:43G-28.19 Radiation therapy continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for radiation therapy services that is integrated into the hospital continuous quality improvement program and 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.

(b) New or existing radiation oncology facilities shall be fully accredited by the American College of Radiology or the American College of Radiation Oncology by December 20, 2002 and continuously maintained thereafter.

(c) Copies of the 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 a condition of licensure within 45 days of receipt of the certificate.

8:43G-28.20 Staff education

Requirements for the radiology staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-28.21 (Reserved)

8:43G-28.22 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. 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 participate in protocols of a national multi-institutional pediatric oncology group such as Children's Cancer Group (CCG) or Pediatric Oncology Group (POG).

8:43G-28.23 Independent verification of MRO equipment calibration

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

(b) Existing megavoltage radiation oncology services shall have until December 20, 2000 to achieve initial independent verification of its MRO equipment output and maintain that verification annually thereafter.

8:43G-28.24 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 29. PHYSICAL AND OCCUPATIONAL THERAPY

8:43G-29.1 Physical therapy policies and procedures

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

1. Criteria for patient assessment and treatment plans;

2. Procedures for medical emergencies; and

3. Mechanisms for interdisciplinary communication.

(b) Each patient referred to the physical therapy service by physician's order shall be assessed by a physical therapist. The assessment shall include review of the medical record or medical history. A written plan of care shall be developed, based on the assessment.

(c) Physical therapy assessment and treatment shall be initiated within 48 hours of referral, excluding weekends and holidays.

(d) The physical therapy service shall develop specific criteria for patient assessment and patient treatment that are used by staff in patient contact, documentation, and for quality assurance. Criteria shall include at least the following:

1. Appropriateness of referrals;

2. Timeliness of the initiation of therapy;

3. Implementation of physical therapy orders;

4. Follow-up for patients who have not responded to therapy; and

5. The adequacy of interdisciplinary communication.

(e) The patient assessment and plan of care shall include measurable goals with specified time frames and shall be documented in the medical record. If goals are not met, the reasons why the goals are not met shall be specified in the medical record.

(f) Each physical therapy treatment shall be documented in the patient's medical record. A note shall be entered into the medical record at least weekly, or more frequently if there is a significant change in the patient's status or treatment needs.

(g) The physical therapist shall discuss the plan of care with the patient and family, if possible.

8:43G-29.2 (Reserved)

8:43G-29.3 Physical therapy staff qualifications

(a) The physical therapy service shall be under the clinical direction of a physical therapist licensed by the New Jersey State Board of Physical Therapy.

(b) A medical staff committee or a physician shall be responsible for clinical services in the physical therapy service.

(c) A copy of each physical therapist's and physical therapist assistant's license shall be conspicuously posted in the physical therapy service.

8:43G-29.4 (Reserved)

8:43G-29.5 Physical therapy staff time and availability

There shall be at least a ratio of one physical therapist to supervise every two physical therapist assistants, or, with a waiver from the New Jersey State Board of Physical Therapy, one physical therapist to supervise every three physical therapist assistants.

8:43G-29.6 Physical therapy patient services

(a) Physical therapy services shall be available on-site.

(b) The physical therapy service shall offer services at least five days a week, excluding holidays.

(c) Visual privacy shall be offered and provided to all patients during evaluation and treatment, when clinically indicated.

(d) Provisions for auditory privacy shall be made for all patients during evaluation and treatment, when clinically indicated.

(e) On discharge, patients shall receive written instructions regarding a home program of treatment, if clinically indicated. The instructions and their receipt shall be documented in the medical record.

8:43G-29.7 (Reserved)

8:43G-29.8 Physical therapy space and environment

(a) Staff of the physical therapy service shall be given space for developing documentation and storing reference books and personal items.

(b) Privacy shall be provided for patients and staff when they need to change clothing before or after treatment.

(c) There shall be lavatories with handwashing facilities in an accessible location, handicapped accessible, handicapped adapted, and well-ventilated.

8:43G-29.9 Physical therapy supplies and equipment

(a) All equipment shall be clean and in good repair.

(b) Physical therapy equipment shall be stored in a safe and accessible place. It shall not be stored in public walkways and hallways.

(c) Call bells shall be provided to patients in the physical therapy service who are not under visual supervision.

8:43G-29.10 Physical therapy staff education

Requirements for the physical therapy education program should be as provided in N.J.A.C. 8:43G-5.9.

8:43G-29.11 (Reserved)

8:43G-29.12 Physical therapy quality improvement methods

There shall be a program of quality improvement for physical therapy that is integrated into the hospital continuous quality improvement program and 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.

8:43G-29.13 Occupational therapy policies and procedures

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

1. Criteria for patient assessment and treatment plans;

2. Emergency procedures for medical emergencies; and

3. Mechanisms for interdisciplinary communication.

(b) Each patient referred to the occupational therapy service by physician's order shall be assessed by an occupational therapist. The assessment shall include review of the medical record. A written plan of care shall be developed, based on the assessment.

(c) Occupational therapy assessment and treatment shall be initiated within 72 hours of referral, excluding weekends and holidays.

(d) The occupational therapy service shall develop specific criteria for patient assessment and patient treatment that are used by staff in patient contact, documentation, and for quality assurance. Criteria shall include at least the following:

1. Appropriateness of referrals;

2. Timeliness of the initiation of therapy;

3. Implementation of occupational therapy orders;

4. Follow-up for patients who have not responded to therapy; and

5. The adequacy of interdisciplinary communication.

(e) The patient assessment and plan of care shall include measurable goals with specified time frames and shall be documented in the medical record. If goals are not met, the reasons shall be specified in the medical record.

(f) Each occupational therapy treatment shall be documented in the patient's medical record. A note shall be entered into the medical record at least weekly, or more frequently, if there is a significant change in the patient's status or treatment needs.

(g) The occupational therapist should discuss the plan of care with the patient and family, if possible.

(h) Hospitals that contract with an occupational therapy service shall ensure compliance with N.J.A.C. 8:43G-29.13 through 29.23.

8:43G-29.14 (Reserved)

8:43G-29.15 Occupational therapy staff qualifications

(a) The occupational therapy service shall be under the clinical direction of an occupational therapist registered by the American Occupational Therapy Association.

(b) A medical staff committee or a physician shall be responsible for clinical services in the occupational therapy service.

(c) All occupational therapists shall be registered and all certified occupational therapy assistants shall be certified by the American Occupational Therapy Association.

8:43G-29.16 (Reserved)

8:43G-29.17 Occupational therapy patient services

(a) Occupational therapy services shall be available on-site.

(b) The occupational therapy service shall have the capacity to offer services, when required by a physician's order, at least five days a week, excluding holidays.

(c) Provisions for auditory privacy shall be made for all patients during evaluation and treatment, when clinically indicated.

(d) On discharge, patients shall receive written instructions regarding a home program of treatment, if clinically indicated. The instructions and their receipt shall be documented in the medical record.

8:43G-29.18 (Reserved)

8:43G-29.19 Occupational therapy space and environment

(a) Privacy shall be provided for patients and staff when they need to change clothing before, during, or after treatment.

(b) Staff of the occupational therapy department shall be given space for developing documentation and storing reference books and personal items.

(c) There shall be lavatories with handwashing facilities that are in an accessible location, handicapped accessible, handicapped adapted, and well ventilated.

8:43G-29.20 Occupational therapy supplies and equipment

(a) All equipment shall be clean and in good repair.

(b) Occupational therapy equipment shall be stored in a safe and accessible place. It shall not be stored and used in public walkways and hallways.

(c) Call bells shall be provided to patients in the occupational therapy department who are not under visual supervision.

8:43G-29.21 Occupational therapy staff education

Requirements for the occupational therapy education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-29.22 (Reserved)

8:43G-29.23 Occupational therapy continuous quality improvement methods

There shall be a program of continuous quality for occupational therapy that is integrated into the hospital continuous quality program and 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.

SUBCHAPTER 30. RENAL DIALYSIS

8:43G-30.1 Scope of renal dialysis standards

These standards shall apply to both hemodialysis and peritoneal dialysis units. In addition to the rules of this subchapter, hospitals providing inpatient renal dialysis services or an on-site, separate designated unit or service for ambulatory patients shall also comply with N.J.A.C. 8:43A-24 in accordance with N.J.A.C. 8:43G-30.3 and 30.4.

8:43G-30.2 Definitions

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

"Ambulatory dialysis" means the performance of a regular course of maintenance dialysis therapy on an outpatient basis.

"Inpatient dialysis" means dialysis therapy provided to either:

1. A hospitalized individual who abruptly sustains loss of kidney function, in whom dialysis is required as a temporary life-supporting measure and in whom recovery of kidney function is expected; or

2. A hospitalized individual with end stage renal disease who requires a regular course of maintenance dialysis therapy.

"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.

8:43G-30.3 General provisions; inpatient renal dialysis services

Hospitals providing inpatient renal dialysis services shall comply with both the rules of this subchapter and with the rules at N.J.A.C. 8:43A-24, with the exception of 24.7, 24.13 and 24.15.

8:43G-30.4 General provisions; ambulatory renal dialysis services

Hospitals providing an on-site, separate, designated unit or service for ambulatory renal dialysis patients shall comply with both the rules of this subchapter and with the rules at N.J.A.C. 8:43A-24.

8:43G-30.5 Physical plant requirements for inpatient renal dialysis units

(a) The treatment area for inpatient renal dialysis services shall be an open planned area separated from administrative and service areas.

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

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

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

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

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

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

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

(c) Cubicle curtains around each patient station shall be provided for privacy and dignity.

(d) A nurses' station shall be located within the open treatment dialysis area for a unit of four or more dialysis stations and shall provide visibility of all patients' stations. This visibility condition shall apply to those facilities licensed March 6, 2006 and thereafter. However, in the case of new construction or renovation involving at least 25 percent of the physical plant, hospital-based ambulatory renal dialysis units shall be required to conform to the standards of this section.

(e) Charting facilities for nurses and doctors shall be provided.

(f) Hand washing facilities shall be provided at a ratio of one hand sink per every four dialysis stations and shall be distributed throughout the dialysis area.

(g) The following requirements shall be met for the size and location of each treatment area utilizing two or more dialysis stations for inpatient renal dialysis services:

1. A support space, which shall be adjacent to the open treatment area;

2. Separate clean and soiled work or utility rooms shall be available within a reasonable distance. These facilities may be shared;

3. A separate janitor's closet, which may be shared, shall be provided for in the renal suite. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment;

4. If a separate employee kitchen or dining area is provided in the suite, it shall be separated from the patient area and shall not be utilized by patients;

5. A lounge, locker room and staff toilet with hand washing facilities, which shall be available for staff;

6. A medication station that includes a work counter with hand washing facilities, refrigerator, and locked storage for syringes, biologicals and drugs, and which may be either:

i. A room or area designated to store and prepare individual patients' medication for administration, located in a space that is under the nursing staff's visual control; or

ii. A room or area designated to prepare individual patients' medication for administration, in which patients' medication is self-contained in a medication-dispensing machine, such as a Pyxis system or other such system approved for use by the Department, and which may be located at the nurses' station, in a clean work room, or in another space that is under direct control of the nursing or pharmacy staff;

7. A storage room or rooms, which shall be located either within or outside of the suite, which shall house the supplies and equipment necessary to maintain the machines for the dialysis suite. At least one week of operational supplies must be available in the facility;

8. Storage space for medical waste shall be provided until it is properly disposed;

9. If patient toilet rooms are provided, they shall have doors equipped with hardware which will permit access by staff in any emergency; and

10. If home training is provided, patient education rooms or areas shall be equipped with a sink for hand washing.

(h) For hospitals using contract or outside vendors to manage inpatient dialysis services, the hospital shall assure that appropriate documentation from the vendor verifying the training competencies and health status of staff is available upon request of the Department**.**

8:43G-30.6 Staffing requirements for inpatient dialysis services

(a) A nephrologist shall be present prior to the initiation of the following:

1. A patient's first inpatient dialysis treatment;

i. Chronic dialysis patients who are dialytically stable and who have been admitted to the hospital for conditions unrelated to their end stage renal disease shall be exempt from (a) 1 above; and

2. Emergency dialysis to a patient with a life-threatening situation, as determined by medical staff

i. In the case of emergency dialysis, the nephrologist shall be present during the dialysis and until the patient is deemed stable.

(b) The staffing ratio in the inpatient dialysis setting shall be no greater than one registered nurse to three patients, except in the critical care setting which shall be a ratio of one to one. Staffing shall be increased if warranted by the acuity needs of the patients.

(c) In those instances where the staffing ratio requirement is one to one, a registered nurse with a minimum of six months experience in hemodialysis, obtained within the last 24 months, shall provide the service. In those instances where the staffing requirement is other than one to one, for

the first three patients, a registered nurse meeting the requirement identified above shall provide the treatments.

(d) An inpatient facility providing dialysis services shall have at least one registered nurse providing treatments to the first three patients. There shall be an additional registered nurse, licensed practical nurse, or trained technician to assist the required registered nurse for the next three patients. There shall be two additional staff, one of which is a registered nurse, for each additional group of one to six patients.

8:43G-30.7 Inpatient care plan

(a) A written plan of care for each patient shall be developed by a multidisciplinary team consisting of, at least, a nephrologist, a registered professional nurse, a dietitian, and a licensed social worker (the current outpatient dialysis care plan for previously diagnosed ESRD patients may be used to meet the requirement for the social worker review). The plan of care shall specify goals and expected outcomes.

(b) The written care plan for each inpatient dialysis patient shall be discussed with the patient and/or family, and implemented within 24 hours of admission to the facility

SUBCHAPTER 31. RESPIRATORY CARE

8:43G-31.1 Respiratory care structural organization; definitions

(a) The respiratory care service shall be represented on hospital committees responsible for neonatal, pediatric and adult intensive care, patient care, and infection control.

(b) The following term, when used in this subchapter, shall have the following meaning:

"Licensed respiratory care practitioner" means an individual who qualified and passed the National Board of Respiratory Care Entry Level Examination and is licensed by the State Board of Respiratory Care in accordance with N.J.A.C. 13:44F.

8:43G-31.2 Respiratory care policies and procedures

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

1. A system for the reissuing and discontinuing of all respiratory therapy orders;

2. The duties and responsibilities of respiratory care practitioners;

3. The education, training, and experience requirements of respiratory care practitioners qualified to initiate and maintain therapies and in which special care units they may work;

4. Procedures for control of infection, the spread of infection, and electrical, explosive, and mechanical hazards; and

5. Protocols that encourage multidisciplinary input into the patient's written plan of care.

(b) Verbal or telephone respiratory care orders within the scope of practice of the licensed respiratory care practitioner shall be accepted and recorded by a licensed respiratory care practitioner.

(c) There shall be a protocol whereby the nurse is informed of any verbal or telephone order that is taken by the licensed respiratory care practitioner.

8:43G-31.3 Respiratory care staff qualifications

(a) There shall be a physician director of respiratory care or pulmonary medicine who is board certified or board eligible in pulmonary medicine, and who is responsible for all respiratory care rendered in the hospital.

(b) There shall be an administrative director of respiratory care who is licensed by the New Jersey State Board of Respiratory Care.

8:43G-31.4 (Reserved)

8:43G-31.5 Respiratory care staff time and availability

(a) There shall be at least one licensed respiratory care practitioner assigned primarily to patients in licensed critical care units. Assignments shall be based on the acuity level of patient illness assessed each shift.

(b) There shall be at least one licensed respiratory care practitioner in the hospital or on call, at all times, in addition to the one who is primarily assigned to patients in the critical care unit.

8:43G-31.6 (Reserved)

8:43G-31.7 Respiratory care patient services

(a) There shall be an organized program for teaching patients to administer their own therapy, with adequate supervision and documentation, in any case where it is appropriate for the patient and where the patient is able to receive and follow therapy instructions.

(b) Written treatment plans, and respiratory therapy goals shall be written by the licensed respiratory care practitioner. The written treatment plans shall supplement the respiratory care orders written by physicians and become part of the medical record.

8:43G-31.8 (Reserved)

8:43G-31.9 Respiratory care space and environment

(a) There shall be adequate space available to store all equipment not in routine use. No respiratory care equipment shall be stored in hallways.

(b) There shall be office space dedicated to members of the respiratory care service.

8:43G-31.10 (Reserved)

8:43G-31.11 Respiratory care supplies and equipment

(a) The respiratory care service shall have equipment available to evaluate respiratory therapy.

(b) Pulse oximeters and end-tidal CO sub2 monitors shall be available for patients in the hospital who have a medical condition that requires oxygen and carbon dioxide monitoring.

(c) There shall be a documented system for preventive maintenance of all respiratory therapy equipment.

(d) All mechanical and electrical equipment shall be tested before using for the first time or after repairs.

8:43G-31.12 Respiratory care staff education

Requirements for the respiratory care education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-31.13 (Reserved)

8:43G-31.14 Respiratory care continuous quality improvement methods

There shall be a program of continuous quality improvement for respiratory care that is integrated into the hospital continuous quality improvement program and 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.

SUBCHAPTER 32. SAME-DAY STAY

8:43G-32.1 Scope

The standards set forth in this subchapter apply only to hospitals that have a separate, designated unit or service for same-day stay.

8:43G-32.2 Same-day surgery services structural organization

(a) There shall be an organizational chart or alternative documentation clearly delineating the lines of responsibility, authority, and communication for the same-day surgery service and, if the same-day medical service is a separate entity, the lines of communication between the two services.

(b) There shall be a mechanism for approving policies and procedures and evaluating and reviewing the activities of the same-day surgery service.

8:43G-32.3 Same-day surgery services policies and procedures

(a) The same-day surgery service shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. They shall include at least:

1. Infection control practices;

2. Criteria for the types of patients who may be admitted for same-day surgery;

3. Categories of surgical procedures that may be performed on a same-day basis;

4. When, where, and by whom preadmission testing may be performed;

5. Minimum requirements for preadmission testing for all types of anesthesia;

6. A system for handling medical and non-medical emergencies.

7. A system for securing the belongings and valuables of the patient;

8. Criteria and procedures for discharging a patient, which includes nursing assessments of self-care capability and who is responsible for discharging the patient; and

9. A requirement that patients who receive anesthesia, excluding minor local blocks, not drive themselves home after discharge and are accompanied home by a responsible adult. If the patient fails to comply with the requirement, the circumstances shall be documented in the patient's medical record.

(b) The policies and procedures for the postanesthesia care unit shall apply to same-day surgery service.

(c) A registered professional nurse shall be assigned to circulating nurse duties in each room where same-day surgery is being performed.

(d) When a same-day surgery patient is admitted to the hospital as an in-patient, a statement shall be made in his or her same-day medical record giving the reason for admission.

8:43G-32.4 Same-day surgery services staff qualifications

(a) There shall be a physician director who has clinical responsibility for the same-day surgery service who is board certified. Certification shall be by a board of the American Board of Medical Specialists. This may be the same person who is the physician director of the surgical service.

(b) If there is a postanesthesia care unit, or postoperative unit dedicated to same-day surgery patients, there shall be a registered professional nurse present whenever a patient is in the unit. Additional nursing staff shall be assigned based on the volume and case mix of patients in the unit.

(c) All registered professional nurses in the postanesthesia care unit or postoperative unit dedicated to same-day surgery patients shall have training in basic cardiac life support.

8:43G-32.5 Same-day surgery patient services

(a) There shall be documentation of perioperative patient education.

(b) There shall be a system to ensure checking of each patient's preoperative record for completeness before the procedure begins.

(c) Physician orders, specific for each patient, shall govern the postoperative care of each patient.

(d) After the surgical procedure and before discharge, the patient and/or significant other shall receive written and oral instructions on self-care, follow-up, signs and symptoms to be reported to the surgeon, and how to report signs and symptoms.

(e) The medical record for same-day surgery patients shall include at least:

1. The patient's written informed consent;

2. A preoperative note by the physician, dentist, or podiatrist, which includes the surgical plan;

3. A preoperative anesthesia note by the anesthesiologist, if applicable;

4. Documentation of the history and physical examination performed by a physician or clinical practitioner within 30 days, including all updates and assessments as set forth at N.J.A.C. 8:43G-16.6(b), prior to the procedure;

5. Preadmission testing results;

6. A preoperative nursing assessment;

7. A perioperative nurses' note that describes the patient's condition during the procedure;

8. A medication record reflecting the drug given, date, time, dosage, route of administration, and signature and status of individual administering the drug;

9. Any physician orders;

10. The surgeon's postoperative note on the procedure;

11. The surgeon's discharge note, written prior to discharge from the hospital, which describes the disposition of the patient and discharge instructions; and

12. Nurses' notes that describe the patient's postoperative progress.

8:43G-32.6 (Reserved)

8:43G-32.7 Same-day surgery services space and environment

(a) If same-day surgery is performed in a suite dedicated to same-day patients, the suite shall be maintained as a closed unit. Access to the restricted zone of the surgical suite shall be through or past a control center.

(b) There shall be a waiting area for families and significant others of patients undergoing same-day surgery.

8:43G-32.8 (Reserved)

8:43G-32.9 Same-day surgery services continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for same-day surgery that is integrated into the hospital continuous quality improvement program and 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. Continuous quality improvement shall include monitoring at least:

1. Complications;

2. Inpatient admissions from the same-day surgery service;

3. Related admissions subsequent to discharge from same-day surgery;

4. Incidents; and

5. Medical emergencies.

(b) The infection control program shall monitor infection control practices and outcomes for same-day surgery services. If same-day surgery patients are treated on inpatient units, the infection control program for those units shall fulfill this requirement.

8:43G-32.10 Same-day medical services standards; scope

(a) The standards set forth in N.J.A.C. 8:43G-32.11 through 32.20 apply only to hospitals that have a separate, designated unit or service for medical same-day stay.

(b) Same-day medical services are defined as elective treatments, diagnostic and non-surgical procedures as defined in the ICD-9-CM codes, with the patient being discharged in a routine status before midnight of the day of admission or treatment.

8:43G-32.11 Same-day medical services structural organization

There shall be an organizational chart or alternative documentation clearly delineating the lines of responsibility, authority, and communication for the same-day medical service and, if the same-day surgery service is a separate entity, the lines of communication between the two services.

8:43G-32.12 Same-day medical services policies and procedures

(a) The same-day medical service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. They shall include at least:

1. Infection control practices;

2. Criteria for the types of patients who may be admitted for same-day medical services;

3. Categories of procedures and treatments that may be performed on a same-day basis;

4. A system for handling medical and non-medical emergencies;

5. A system for securing the belongings and valuables of patients; and

6. Criteria and procedures for discharging a patient.

(b) When a same-day medical patient is admitted to the hospital as an inpatient, a statement shall be made in his or her same-day medical record giving the reason for admission.

8:43G-32.13 Same-day medical services staff time and availability

Same-day medical patients shall receive nursing care based on their acuity.

8:43G-32.14 Same-day medical services patient services

(a) There shall be a medical record for each patient admitted for same-day medical care. This record shall include, at least, documentation of a history and physical examination, results of tests, all treatments and the patient's response to treatments rendered.

(b) There shall be physician orders, specific for each patient, that govern the care of each same-day medical service patient.

8:43G-32.15 (Reserved)

8:43G-32.16 Same-day medical services space and environment

There shall be waiting areas for families and significant others of patients undergoing same-day medical procedures.

8:43G-32.17 (Reserved)

8:43G-32.18 Same-day services education

Requirements for the same-day services education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-32.19 (Reserved)

8:43G-32.20 Same-day medical services continuous quality improvement methods

(a) There shall be a program of continuous quality improvement for same-day medical service that is integrated into the hospital continuous quality improvement program and 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.

(b) The infection control program shall monitor infection control practices and outcomes for same-day medical patients. If same-day medical patients are treated on inpatient units, the infection control program for those units shall fulfill this requirement.

8:43G-32.21 Observation services; scope

The standards set forth in N.J.A.C. 8:43G-32.22 and 32.23 shall apply to a service, unit, or area(s), separate from the emergency department and designated by the hospital for the purpose of monitoring and/or observing patients who have not yet been determined to require inpatient admission.

8:43G-32.22 Observation service policies and procedures

(a) The hospital shall have a clearly defined plan and written policies and procedures for the use of an observation service that are reviewed at least once every three years, revised as needed, and implemented. These policies and procedures shall include at least:

1. Criteria for admission to and discharge from the service;

2. Professional nursing supervision and nurse staffing;

3. Criteria for length of stay (which shall be less than 24 hours total stay within the hospital unless the patient has been admitted);

4. Quality assurance and review; and

5. Use of beds on an inpatient unit for observation as set forth at N.J.A.C. 8:43G-32.23(b).

8:43G-32.23 Observation service space and environment

(a) Prior to implementation, the hospital shall inform the Department of Health and Senior Services in writing of the location and the number of spaces in the service.

(b) The hospital may mix observation beds and inpatient beds in the same room provided the following requirements are met:

1. Observation patients are included in the patient-to-nurse staffing ratio of the nursing unit on which the observation patient is placed; and

2. Policies and procedures specific to the use of an inpatient unit for observation purposes are in place prior to the commencement of this practice.

(c) Observation beds shall not be considered licensed beds unless observation patients are placed in licensed beds pursuant to (b) above.

SUBCHAPTER 33. SOCIAL WORK

8:43G-33.1 Social work structural organization

(a) Each hospital shall have an organized social services department or function, with social services performed by social workers under the direction of a licensed social worker.

(b) There shall be an organizational chart or alternative documentation clearly delineating the lines of responsibility, authority and communication for the social services department or function.

8:43G-33.2 Social work policies and procedures

(a) The social work department shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. The policies and procedures concerning the scope of social work services shall address the following areas: counseling, discharge management and planning, social work assessment, consultation and referral, patient advocacy, community liaison, and education.

(b) The social work department shall have a protocol to ensure that social work services are offered to all patients who need or request them.

(c) The social services department or function shall have criteria for identifying at the time of admission and promptly assessing high-risk patients in need of psychosocial intervention and/or discharge planning.

(d) The social work department shall participate in the development and review of the hospital's agreements with extended and long-term care facilities.

8:43G-33.3 Social work staff qualifications

(a) There shall be a director of the social work department who is licensed by the New Jersey State Board of Social Work Examiners in compliance with rules at N.J.A.C. 13:44G.

(b) Each social worker shall be certified or licensed by the New Jersey State Board of Social Work Examiners.

8:43G-33.4 (Reserved)

8:43G-33.5 (Reserved)

8:43G-33.6 Social work patient services

(a) There shall be a system for clinical staff to refer patients directly to the social work department.

(b) The social worker shall consult with members of other disciplines in providing patient care services.

(c) Each patient who has received social work intervention shall be informed that he or she may call the social work department with questions after discharge.

(d) Families or guardians shall be included in services provided by the social work department, where indicated.

(e) The social work department shall assist patients directly or indirectly in identifying the need for, implementing, and verifying guardianship as part of discharge planning.

(f) The social work department shall coordinate child-abuse reporting and follow-up services with appropriate follow-up agencies in accordance with N.J.S.A. 9:6-1 et seq. The department shall participate in reporting and follow-up services for other victims of abuse.

(g) When a patient is transferred to another health care facility or linked to another health care agency after discharge, the social work department shall assure that relevant social work services documentation or information, if available, is provided to that agency or facility in order to assure continuity of care.

(h) When social work intervention is provided, the social work department shall enter into the medical record:

1. The reason for intervention;

2. The name or names of social workers involved and dates of intervention;

3. A social work assessment;

4. A treatment plan and referrals; and

5. Notes reflecting interventions before discharge.

(i) Social work staff shall be included in multidisciplinary patient care conferences or rounds.

8:43G-33.7 (Reserved)

8:43G-33.8 Social work space and environment

(a) All reasonable efforts shall be made for privacy in patient and family interviews and in the handling of confidential phone calls by social workers.

(b) Social work department files on patients shall be kept physically secure and confidential.

8:43G-33.9 Social work staff education and training

Requirements for the social work staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-33.10 Social work continuous quality improvement methods

There shall be a program of continuous quality improvement for social work that is integrated into the hospital continuous quality improvement program and pertains to the scope of social work services provided. The program shall include 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.

SUBCHAPTER 34. SURGERY

8:43G-34.1 Surgery structural organization

There shall be an organizational chart, or alternative documentation that delineates the lines of authority, responsibility, and accountability of staff in surgery services.

8:43G-34.2 (Reserved)

8:43G-34.3 Surgery policies and procedures

(a) Surgery services shall have written policies and procedures that are reviewed at least every three years, revised more frequently as needed, and implemented. They shall include at least:

1. Aseptic practices;

2. Infection control policies for the surgical suite, including attire which is commercially laundered;

3. Processing, packaging, and sterilization of materials in the suite; and

4. Special procedures for handling of trash from the surgical suite.

(b) The postanesthesia care unit shall maintain its own specific policies and procedures. Where applicable, these policies and procedures shall be integrated with the policies and procedures of the surgical suite.

(c) A policies and procedures manual governing the overall functions and responsibilities of the surgical suite shall be available to surgical suite staff whenever the suite is open.

(d) There shall be a written procedure established 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.

(e) There shall be 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.

8:43G-34.4 Surgery staff qualifications

(a) There shall be a physician director who is clinically responsible for surgical services and is board certified.

(b) There shall be a person with administrative responsibility for the surgical service.

(c) Each surgical suite shall have available a roster of physicians with delineation of current surgical privileges, including those with temporary privileges.

(d) The hospital shall maintain a list of surgical procedures that require the presence of a physician to act as first assistant.

8:43G-34.5 Surgery staff time and availability

(a) A registered professional nurse shall be assigned to circulating nurse duties in each room where surgery is being performed.

(b) All registered professional nurses in the unit shall maintain certification in Basic Cardiac Life Support.

(c) During scheduled hours of operation, personnel who have received special training in cleaning the surgical suite shall be assigned to the surgical suite for cleaning and related duties.

8:43G-34.6 Surgery patient services

(a) A patient identification system shall be implemented and patient identification shall be verified prior to any surgical procedure.

(b) 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.

(c) 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 hospital policy.

(d) There shall be a system to ensure that surgical patients' personal effects are secured during surgery.

(e) The surgery services staff shall take precautions to prevent patient falls and injuries during transportation, transfer, and positioning through the use of side rails or restraint straps, and control devices on stretchers and operating tables.

(f) Each surgical patient shall have a medical record in accordance with the medical records policies of the hospital. The medical record shall be available to surgical suite personnel prior to surgery and shall include at least:

1. A written informed consent form signed by the patient or legal guardian or authorized person according to hospital policy that includes identification of the physician(s) performing the procedure prior to all procedures requiring informed consent;

2. A completed preoperative checklist;

3. A medical history and the results of a physical examination; and

4. Diagnostic tests results as determined by hospital policy.

(g) The surgical suite nursing staff shall make a preoperative note or notes for each surgical patient, which is part of the medical record and follows the patient to the patient care unit. The note shall describe intraoperative nursing care and patient reactions while in the operating suite.

(h) Operative reports shall be dictated or written in the medical record immediately after surgery.

(i) The completed operative report shall be reviewed for accuracy, signed and dated by the surgeon and filed in the medical record as soon as possible after surgery.

(j) There shall be a system in place for obtaining frozen section results on a timely basis.

(k) There shall be documentation of preoperative patient education.

8:43G-34.7 Surgery space and environment

(a) The surgical suite shall be maintained as a closed unit. Access to the surgical suite shall be restricted in accordance with hospital policies and procedures.

(b) All staff in the surgical suite shall be attired in scrub attire. Individuals who are permitted limited access shall be attired according to hospital infection control policies.

(c) Procedures shall be in place 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.

(d) Procedures shall be in place 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.

8:43G-34.8 Surgery supplies and equipment

(a) Emergency equipment available in the surgical suite shall include at least the following:

1. An 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. A difficult airway container or cart shall be immediately available for handling emergencies. The following items are required for inclusion in the difficult airway container or cart:

i. Manual breathing apparatus;

ii. A cardiac monitor;

iii. A defibrillator;

iv. A portable suction setup;

v. A thoracotomy set; and

vi. A tracheostomy set and endotracheal tubes including sizes adaptable to newborns, infants and children; and

3. There shall be a mechanism for testing the emergency equipment on a regular basis and documenting that it is in working condition.

(b) There shall be a system to ensure that sterile supplies are immediately available. This system shall include rotation and inventory of packaged items; evaluation of the integrity of drapes, gowns, and sterile supplies; and periodic review of policies and procedures for processing, packaging, and sterilization of materials.

(c) All used surgical suite linens and apparel shall be laundered between uses by the hospital laundry service. Employees shall not take these materials home to wash them.

(d) All surgical suite equipment and supplies shall be maintained in a clean condition, without tears or tape.

(e) All surgical staff shall comply with the current universal precautions as set forth in the Centers for Disease Control and Prevention Guideline for Handwashing and Hospital Environmental Control (Infection Control and Hospital Epidemiology 1999, 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.

(f) Clean linen shall be stored separately from soiled laundry in the surgical suite.

8:43G-34.9 Surgery staff education

Requirements for the surgery staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

8:43G-34.10 (Reserved)

8:43G-34.11 Surgery continuous quality improvement

(a) There shall be a complete and current record of all surgical procedures.

(b) The hospital'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 hospital 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.

8:43G-34.12 (Reserved)

SUBCHAPTER 35. POSTANESTHESIA CARE

8:43G-35.1 Postanesthesia care policies and procedures

(a) 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. They shall include at least:

1. Criteria for admission to and discharge from the unit;

2. Delineation of primary medical responsibility for postanesthesia and postsurgical care of the patient in the unit;

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; and

7. Requirements for documentation of patient status.

8:43G-35.2 Postanesthesia care staff qualifications

(a) There shall be a physician director with overall responsibility for postanesthesia care. The physician director may also be the director of anesthesia services.

(b) There shall be a registered professional nurse with administrative responsibility for nursing care 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 functions;

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 training in Advanced Cardiac Life Support.

8:43G-35.3 Postanesthesia care staff time and availability

(a) There shall be at least two health care personnel, one of whom is a registered professional nurse and the other of whom is either a licensed practical nurse, a registered professional nurse, or a physician, present whenever a patient is in the postanesthesia care unit.

(b) There shall be a ratio of at least one registered professional nurse for every three patients in the postanesthesia care unit.

8:43G-35.4 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.

(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, unless such monitoring is not clinically feasible for the patient.

(f) Each patient 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 medical record maintained for each patient in the postanesthesia care unit shall include at least such preoperative data as allergies, physical and mental impairments, prostheses, electrocardiogram, vital signs, radiologic findings, laboratory values, drug use, and mobility limitations.

(i) The Post Anesthesia Care Unit record maintained for each patient in the postanesthesia care unit shall include at least such postoperative data as the patient's general condition, respiration, consciousness, circulation**,** temperature, 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. 8:43G-35.1 (a) 1.

8:43G-35.5 (Reserved)

8:43G-35.6 Postanesthesia care supplies and equipment

(a) Postanesthesia care units shall be adjacent to or within the operating suite and the obstetrics suite.

(b) The postanesthesia care unit shall be maintained as a closed unit. Access to the postanesthesia care unit shall be in accordance with hospital 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 hospital infection control policies**.**

(d) Equipment 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. 8:43G-35.4(g) shall be made available. Provisions to ensure the patient's privacy shall be made.

8:43G-35.7 Postanesthesia care staff education and training

Requirements for the postanesthesia education program shall conform to the standards set forth in N.J.A.C. 8:43G-5.9.

8:43G-35.8 (Reserved)

8:43G-35.9 Postanesthesia care continuous quality improvement

(a) The hospital'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 hospital 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 activities shall include at least the monitoring of outcomes for patients receiving anesthetic agents and postdischarge follow-up of surgical procedures**.**

SUBCHAPTER 36. SATELLITE EMERGENCY DEPARTMENTS

8:43G-36.1 Scope

(a) All satellite emergency departments shall be owned and operated by an acute care general hospital and shall comply with the rules in this subchapter and all applicable requirements of 8:43G. All satellite emergency departments shall provide emergency treatment and care within the scope of this subchapter for those patients who are transported by basic life support (BLS) transport service and other ambulatory arrivals.

(b) Satellite emergency departments shall be licensed only to replace the full service emergency department of a licensed general acute care hospital which has approval from the Department to cease operation of all of its licensed acute care beds. The satellite emergency department shall be located in as close proximity to the closed full service emergency department as is possible. This location shall require the prior written approval of the Department.

1. For each full service emergency department which has closed, only one satellite emergency department shall be licensed to provide care.

2. Priority for licensing satellite emergency departments shall be given to the entity or its parent which was previously licensed to operate the full service emergency department or to an entity with a formal affiliation to one of the latter at the time licensing of the satellite emergency department is requested.

(c) The Department may consider a waiver to (b) above where the proposed operator of a satellite emergency department is able to demonstrate to the satisfaction of the Department that its proposed location will serve to eliminate or substantially mitigate problems of access to appropriate emergency care affecting a community or communities.

(d) Although a satellite emergency department may provide care and services to all patients, cases more appropriately treated in an acute care hospital emergency department include the following:

1. Patients attended by advanced life support (ALS) personnel/mobile intensive care unit (MICU) personnel and requiring ALS/MICU care and services;

2. Individuals with altered mental status or under the influence of alcohol or other substances; and

3. Pregnant women greater than 20 weeks with conditions relating to pregnancy.

(e) A certificate of need application and certificate of need approval is not required in order for a licensed hospital to institute, construct, expand or operate a satellite emergency department. However, a licensed hospital which chooses to establish a satellite emergency department shall make application for licensure to the Certificate of Need and Acute Care Licensing Program as required in N.J.A.C. 8:43G-2.2(a) and comply with the requirements of N.J.A.C. 8:43G-2.2 through 2.11. If the satellite emergency department applies for licensure as a free-standing ambulatory care facility, it shall also meet the applicable requirements set forth in N.J.A.C. 8:43A.

(f) A satellite emergency department may be located in a building formerly licensed as an acute care hospital or another building and shall comply with the physical plant requirements specified at N.J.A.C. 8:43G-36.15.

(g) The Department shall charge a non-refundable biennial inspection fee of $2,000 and an annual licensure fee of $2,500 for the operation of a satellite emergency department.

(h) Each satellite emergency department shall provide services 24 hours per day, seven days per week during the first full year after licensing. After one year, if the facility can document a low utilization of patients during any eight hour period, it may cease operation during that time period, following Department of Health and Senior Services (DHSS) approval. In no case shall a satellite emergency department operate less than 16 hours per day, seven days per week after the first year of licensing. Policies and procedures addressing after hours care shall be developed by the satellite emergency department or owner/operator hospital and approved by the DHSS prior to revising hour of operation.

1. The satellite emergency department may apply to the Department to reduce hours of operation to 16 hours per day after one year of operation. Such requests shall include documentation of low utilization as defined in N.J.A.C.8:43G-36.2.

(i) Hospital owned and operated satellite emergency departments shall not contain any licensed beds. However, the satellite emergency department may have observation beds, which shall only be used for a time period of not more than 12 hours from time of registration and in the care of patients likely or expected to be discharged home, unless, the patient is awaiting test results or transfer to another facility.

8:43G-36.2 Definitions

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

“Advanced life support” means an advanced level of pre-hospital, inter-hospital, and emergency service care which includes basic life support functions, cardiac monitoring, cardiac defibrillation, telemetered electrocardiography, intravenous therapy, administration of specific medications, drugs and solutions, use of adjunctive ventilation devices, trauma care, and other techniques and procedures authorized by the Commissioner.

“Basic life support” means a basic level of pre-hospital care which includes patient stabilization, airway clearance, cardiopulmonary resuscitation, control of hemorrhage, initial wound care, fracture stabilization, and other techniques and procedures
specified in N.J.A.C. 8:40A-1.2 and authorized by the Commissioner.

“Department” means the New Jersey State Department of Health and Senior Services.

“Licensee” means acute care hospital authorized by the Department of Health and Senior Services to own and operate a satellite emergency department and on whom the responsibility for maintaining acceptable standards in all areas of operation of the satellite emergency department.

“Low utilization” means an average of 16 patients or less over an 8 hour consecutive period of time for the most recent six months prior to the request to reduce hours of operation.

"Satellite emergency department" means a facility, which is owned and operated by a licensed New Jersey general acute care hospital, which shall provide emergency care and treatment for patients.

8:43G-36.3 Services in satellite emergency departments

(a) All laboratory services provided in the satellite emergency department shall comply with the requirements of N.J.A.C. 8:45, Standards for Clinical Laboratory Services, and all radiology services shall comply with applicable requirements of N.J.A.C. 7:28-19, Medical Exposure To Ionizing Radiation by Radiological Technologists.

(b) All satellite emergency departments applying for licensure shall provide the following services:

1. Basic life support emergency care and services;

2. Basic and stat laboratory services including:

i. Arterial blood gases;

ii. Creatinine;

iii. Electrolytes;

iv. Glucose (blood);

v. CBC;

vi. Strep screening;

vii. Urinalysis; and

viii. Pregnancy tests; and

3. Basic radiology services, which shall include at a minimum non-enhanced and non-contrast radiographs.

(c) Services in addition to those in (b) above may be provided at the discretion of the facility.

(d) Although a satellite emergency department may provide care and services to all patients, the following cases are more appropriately treated in an acute care hospital emergency department.

1. Patients attended by advanced life support (ALS) personnel/mobile intensive care unit (MICU) personnel and requiring ALS/MICU care and services;

2. Individuals with altered mental status or under the influence of alcohol or other substances; and

3. Pregnant women greater than 20 weeks with conditions relating to pregnancy.

8:43G-36.4 Child abuse and neglect

Satellite emergency departments shall comply with N.J.A.C. 8:43G-2.13.

8:43G-36.5 Patient rights

Every New Jersey satellite emergency department patient has the same rights as required in N.J.A.C. 8:43G-4 with the exception of N.J.A.C. 8:43G-4.1(a)14. None of the patient rights shall be abridged by the satellite emergency department or the hospital that owns and operates the satellite emergency department. The administrator of the satellite emergency department or the administrator of the hospital licensed to operate the satellite emergency department shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient's rights.

8:43G-36.6 Administrative and structural organization

(a) A satellite emergency department may be licensed as a free-standing ambulatory care facility owned and operated by a hospital or as part of the hospital. If licensed as an ambulatory care facility, it must comply with the general ambulatory care facility requirements set forth in N.J.A.C. 8:43A as well as these rules. If the satellite emergency department is licensed as part of the hospital, it shall comply with the requirements set forth in N.J.A.C. 8:43G-2.5 and the criteria set forth in N.J.A.C. 8:43G-2.11, as well as this subchapter.

(b) An administrator of the satellite emergency department shall be designated in writing.

(c) The satellite emergency department shall have policies and procedures, which pertain to:

1. All staff;

2. Admission and discharge of patients;

3. Procedures for obtaining patient's written consent for all medical treatment;

4. Patient advance directives;

5. Elder abuse;

6. Domestic violence;

7. The ability of family members and significant others to remain with patients during treatment;

8. Referrals to primary care physicians and specialists, to assure access to all appropriate clinical services and specialties even though immediate consultation is not necessary;

9. Transfer Protocol;

i. Written transfer agreements must be in place assuring timely response to accomplish basic and advanced level transfers from a satellite emergency department to an acute care facility;

ii. Transfers requiring basic life support services shall be accomplished by a licensed ambulance in accordance with N.J.A.C. 8:40;

iii. Transfers requiring advanced life support care shall be accomplished with a critical care transport team including a registered nurse and a licensed ambulance in accordance with N.J.A.C. 8:40-6.22; and

iv. Transfers may be by other means as deemed appropriate by the physician;

10. Pharmacy Services, including controlled substances;

11. Procedural Sedation;

12. Infection Control;

13. Dietary;

14. Linens;

15. Housekeeping;

16. Lab Services;

17. Payment Source;

18. Policies and procedures for handling an unexpected influx of patients; and

19. Policies and procedures for maintaining a record of hospital employees, medical staff members, and volunteers who can speak languages other than English or know sign language for the hearing impaired and can provide interpretive services to patients. This record shall include the work shifts of hospital employees.

(d) The satellite emergency department shall maintain a copy of all policies and procedures which apply to the facility onsite.

843G-36.7 Reportable Events

The satellite emergency department shall comply with the requirements of N.J.A.C. 8:43G-5.6.

8:43G-36.8 Administrative and staff qualifications

(a) Physician qualifications for satellite emergency departments are as follows:

1. There shall be a physician director of the satellite emergency department, who may also be the director of the hospital's emergency department, who is board certified in emergency medicine or who has five years of full-time experience in emergency medicine, which may include three years residency in emergency medicine, within the past seven years. If the physician director of the satellite emergency department is not the physician director of the hospital emergency department, then there shall be coordination of all care and services

between the two to ensure care delivery and quality improvement in accordance with N.J.A.C. 8:43G-5.16.

2. Each physician practicing in the satellite emergency department, except residents functioning under supervision as part of a hospital's graduate residency training program, consulting physicians, and private physicians who are attending to their patients in the satellite emergency department, shall meet at least one of the following qualifications:

i. Board certification or current eligibility to be certified in emergency medicine; or

ii. Successful completion of an approved residency program in emergency medicine, family medicine, general internal medicine, general surgery, or general pediatrics; or

iii. Three years of full-time clinical experience in emergency medicine within the past five years.

3. Each physician practicing in the satellite emergency department except residents functioning under direct supervision as part of the hospital's residency program, consulting physicians, and private physicians who are attending to their patients in the emergency department, shall attain provider status in Advanced Cardiac Life Support and either Advanced Pediatric Life Support or Pediatric Advanced Life Support within 12 months of initial assignment, and shall continuously maintain this status thereafter. Physicians who are board certified in emergency medicine shall be exempt from this requirement.

4. Each physician practicing in the satellite emergency department, except residents functioning under direct supervision as part of a hospital's graduate residency program, consulting physicians, and private physicians who are attending to their patients in the satellite emergency department, shall attain provider status in Advanced Trauma Life Support within 12 months of initial assignment, and shall continuously maintain this status thereafter. Physicians who are board certified in emergency medicine shall be exempt from this requirement.

(b) One licensed registered professional nurse certified in Advanced Cardiac Life Support (ACLS), and either Pediatric Advanced Life Support (PALS), Advanced Pediatric Life Support (APLS), or Emergency Nurse Pediatric Course (ENPC), with at least one year of emergency, room experience shall be on duty at all times in the satellite emergency department.

(c) One New Jersey licensed x-ray technician shall be on duty at all times.

(d) One staff person deemed competent by the laboratory director to perform lab tests specified in this chapter shall be on duty at all times.

(e) One current staff person who meets the qualifications identified in (c) and (d) above may be designated responsible for these areas of care and service.

(f) The facility must have policies and procedures in place to address and ensure increased staffing to address increased patient volume and acuity.

8:43G-36.9 Staff Time and Availability

(a) The satellite emergency department shall have all personnel identified in N.J.A.C. 8:43G-36.8(a) onsite at all times during hours of operation.

(b) No patient who comes to the satellite emergency department shall be discharged to home or another facility without being seen and evaluated by qualified medical personnel. This evaluation shall occur within four hours of the patient's coming to the satellite emergency department.

8:43G-36.10 Administrative and Staff Education

The satellite emergency departments shall comply with the requirements of N.J.A.C. 8:43G-5.7 and 5.9.

8:43G-36.11 Occupational health structural organization

The satellite emergency department shall comply with the requirements of N.J.A.C. 8:43G-5.11, 5.12, 5.13, 5.14 and 5.15.

8:43G-36.12 Disaster planning

The satellite emergency department shall comply with N.J.A.C. 8:43G-5.16.

8:43G-36.13 Mandatory Equipment

(a) The following equipment shall be located within the satellite emergency department at all times:

1. Basic and stat laboratory equipment/supplies, with at least the capability to perform the following laboratory testing and evaluation:

    i. Arterial blood gases;

    ii. Creatinine;

    iii. Electrolytes;

    iv. Glucose (blood);

    v. CBC;

    vi. Strep screening;

    vii. Urinalysis; and

    viii. Pregnancy tests;

2. Defibrillator(s) with external pacemaker capability;

3. Advanced airway equipment;

4. Surgical airway equipment;

5. Suction equipment;

6. Obstetric kit with capability to keep patients warm;

7. Emergency chest decompression equipment; and

8. Basic radiology services, which shall include at a minimum non-enhanced and non-contrast radiographs.

8:43G-36.14 Continuous Quality Improvement

(a) The satellite emergency department shall comply with N.J.A.C. 8:43G-5.15.

(b) On a quarterly basis, beginning with the closest calendar quarter after commencing operation, the satellite emergency department shall submit the following information to the Department's Certificate of Need and Acute Care Licensure Program:

1. The total volume of patients for the quarter;

2. Number of transfers to the hospital licensed to operate the satellite emergency department (which statistics shall identify a breakout of all BLS and ALS levels);

3. The number of transfers to other hospitals;

4. The mode of arrival at the satellite emergency department for each patient during the quarter; and

5. The number of transfers for further diagnostic study.

8:43G-36.15 Physical Plant

A building or structure being considered for use as a satellite emergency department, located independent from an acute care hospital shall comply with all the requirements of Use Group B, and section 13.6 of the NFPA 101, 1985 edition, as referenced in N.J.A.C. 8:43G-24.13(a). A satellite emergency department that remains located in a former acute care hospital shall continue to comply with the requirements of Use Group I-2, as noted in section N.J.A.C. 8:43A-19.1 of the Standards for Licensure of Ambulatory Care Facilities.

SUBCHAPTER 37. EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES

8:43G-37.1 Extracorporeal shock wave lithotripsy services

All general hospitals providing extracorporeal shock wave lithotripsy services shall conform to the applicable criteria set forth in this chapter as well as the provisions set forth in N.J.A.C. 8:43A-29.

SUBCHAPTER 38. LONG TERM ACUTE CARE HOSPITALS GENERAL REQUIREMENTS

8:43G-38.1 Scope

(a) Special hospitals providing long term acute care services shall comply with all standards set forth in this subchapter and all applicable provisions of this chapter.

(b) The rules in this subchapter apply to special hospitals providing long term acute care services either as a freestanding facility or as part of a licensed general hospital (hospital within a hospital)

8:43G-38.2 Compliance with rules and laws

(a) All special hospitals providing long term acute care services (LTAC) shall be licensed by the New Jersey Department of Health and Senior Services and comply with the licensing procedures set forth at N.J.A.C. 8:43G-2.

(b) All beds maintained by a special hospital providing long term acute care services shall be licensed as long term acute care beds.

(c) All special hospitals providing long term acute care services shall comply with the rules of the United States Department of Health and Human Services at 42 CFR Part 412 et al. incorporated herein by reference as amended and supplemented.

(d) All special hospitals applying for licensure shall provide or arrange for the provision of the following professional departments, services, facilities or functions:

1. Administration;
2. Anesthesia/Sedation Services;
3. Blood Bank;
4. Central Supply;
5. Clinical and Pathological Laboratories;
6. Dietary Services;
7. Discharge Planning;
8. Employee and Occupational Health;
9. Electrocardiogram Laboratory;
10. Housekeeping and Laundry Services;
11. Infection Control and Sanitation;
12. Medical Library;

13. Medical Records;

14. Medical Services;

15. Medical Staff;

16. Morgue and Autopsy Facilities;

17. Nursing Service;

18. Pharmacy Department;

19. Physical and Occupational Therapy;

20. Physical Plant and Maintenance;

21. Post Anesthesia Care Unit;

22. Quality Assurance;

23. Radiology;

24. Respiratory Therapy Services; and

25. Social Work Department.

(e) Special hospitals providing long term acute care services shall comply with the physical plant requirements at N.J.A.C. 8:43G-24.8. In addition to the standard construction requirements for hospitals, the following shall be required:

1. Ventilation care units shall have piped in oxygen, suction equipment, emergency electrical outlets, and additional square footage for ventilator equipment and supplies; and

2. The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with acceptable engineering practices.

8:43G-38.3 Special hospital policies and procedures

(a) Special hospitals shall have written policies and procedures that are reviewed at least once every three years, revised more frequently as needed, and implemented. They shall include at least:

1. Criteria for admission to, and discharge and transfer from, the hospital;

2. A visitors policy that specifies visiting hours and number of visitors permitted each patient at one time, subject to the discretion of the patient’s physician or primary care nurse;

3. Protocols for transfer and transport of patients within the hospital or from the hospital to another facility, including who shall accompany the patient being transferred or transported;

4. A policy defining the physician specialist and consulting physician to be called for patient emergencies, including a response time for physicians to respond to patient emergencies;

5. Standing orders for patient emergencies;

6. A policy on the removal of a patient's life support system pursuant to N.J.A.C. 8:43G-4; and

7. Educational policies for the patient and families to manage their present and future healthcare needs.

8:43G-38.4 Special hospital staff qualifications

(a) There shall be a physician director with clinical responsibility for the care rendered throughout the facility.

(b) The physician director shall be board certified in internal medicine and licensed or authorized to practice medicine by the New Jersey Board of Medical Examiners.

(c) A physician shall visit each patient at least on a daily basis and as needed.

(d) A physician shall be present in a freestanding special hospital providing LTAC services at all times. A hospital-within-hospital LTAC shall have a physician availability agreement with the host facility, which arranges for physician consultative or care services to be available within 15 minutes of the LTAC's notification of the host facility.

8:43G-38.5 Staff Time and Availability

(a) Nursing staff shall be determined by the acuity of illness of the patient. The hospital shall develop written policies and procedures for determining and relating patient acuity to nursing staff levels.

(b) There shall be a full-time director of nursing or nursing administrator who is a registered professional nurse licensed by the New Jersey Board of Nursing pursuant to N.J.S.A. 45:11-23 et seq. and N.J.A.C. 13:38, who has at least two years of supervisory experience in providing care to patients with acute illness/injury superimposed on complex or multiple co-morbidities.

(c) In the case of specialized care units treating ventilation dependent patients, the facility shall provide staffing for the nursing unit on which the ventilation beds are located that includes the 24 hour per day presence on the unit of at least one registered nurse and the 24 hour per day on site presence of at least one respiratory therapist.

(d) There shall be a mechanism in place to access nutritional support services for advice on both enteral and potential nutritional techniques.

8:43G-38.6 Quality Improvement Methods

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

(b) The continuous quality improvement activities shall include morbidity and mortality conferences.

(c) The continuous quality improvement program shall include review of cases involving removal of life support.