CHAPTER 43G

HOSPITAL LICENSING STANDARDS

Authority

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

Source and Effective Date

R.1995 d.124, effective February 3, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Executive Order No. 66(1978) Expiration Date

Chapter 43G, Hospital Licensing Standards, expires on February 3, 2000.

Chapter Historical Note

Chapter 43G, originally Certificate of Need: Capital Policy, was adopted as R.1986 d.375, effective September 8, 1986. See: 18 N.J.R. 1242(a), 18 N.J.R. 1817(a). The rules concerning Capital Policy were repealed by R.1988 d.114, effective March 21, 1988. See: 19 N.J.R. 2365(b), 20 N.J.R. 645(d).

Chapter 43G, Hospital Licensing Standards, was adopted as R.1990 d.77 through R.1990 d.98, effective February 5, 1990 (operative July 1, 1990). See: 22 N.J.R. 441(b) through 22 N.J.R. 555(a). Pursuant to Executive Order No. 66 (1978), Chapter 43G was readopted as R.1995 d.124. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 33. SOCIAL WORK

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SUBCHAPTER 34. SURGERY

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SUBCHAPTER 35. POSTANESTHESIA CARE

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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 context clearly indicates otherwise.

"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.

"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.

Case Notes

Hospital exemption does not apply to health maintenance organization (HMO) facility property tax status; facility not a hospital as no continuous care provided and it does not exist to further the aims and goals of a functioning hospital. New Brunswick v. Rutgers Community Health Plan, Inc., 7 N.J.Tax 491 (Tax Ct.1985).

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 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 one or more specific categories of patients; 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Case Notes

Nursing home was not "hospital" which was exempt from local property tax. Intercare Health Systems, Inc. v. Cedar Grove Tp., 11 N.J.Tax 423 (1990), affirmed 12 N.J.Tax 273, certification denied 127 N.J. 558, 606 A.2d 369.

8:43G-1.4 Information and complaint procedure

(a) Questions regarding hospital licensure may be addressed to the Inspections Program or the Licensing and Certification Program at the following address:

New Jersey State Department of Health Division of Health Facilities Evaluation and Licensing

CN-367

Trenton, NJ 08625-0367

(609) 588-7725

(b) To make a complaint about a New Jersey licensed hospital or nursing home, 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.

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

Certificate of Need Program

Division of Health Planning and Resources Development

New Jersey State Department of Health

CN 360

Trenton, New Jersey 08625-0360

(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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Case Notes

Licensed beds not interchangeable between categories without hospital licensing board approval. Desai v. St. Barnabas Medical Center, 103 N.J. 79, 510 A.2d 662 (1986).

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:

Director

Licensing, Certification and Standards

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

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- (b) The Department shall charge a non-refundable fee of \$500.00 for the filing of an application for licensure of a hospital and for the annual renewal of the license, and an additional non-refundable fee of \$150.00 for each of the following services, provided, however, that the total fee for the filing of an application for licensure of a hospital and for the annual renewal of the license shall not exceed \$2,000.
 - 1. Obstetric and newborn services;
 - 2. Psychiatric services;
 - 3. Pediatric services;
 - 4. Long-term care unit;
 - 5. Renal dialysis services;
 - 6. Cardiac diagnostic and/or surgical services;
 - 7. Inpatient alcohol abuse treatment services;
 - 8. Inpatient drug abuse treatment services;

- 9. Intensive care unit/coronary care unit; and
- 10. Other services to be designated by the Department.
- (c) 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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8:43G-2.3 Newly constructed or expanded facilities

(a) The application for a license pursuant to N.J.A.C. 8:43G-2.2 for the operation of a new hospital shall include written approval of final construction of the physical plant by:

Health Facilities Construction Service

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

- (b) An on-site inspection of the construction of the physical plant shall be made at the Department's discretion by representatives of the Health Facilities Construction Service 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 Facilities Construction Service of the Department for review and approval prior to the initiation of any work.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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 Facilities Evaluation and Licensing 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 Facilities Evaluation and Licensing 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 Facilities Evaluation and Licensing of the Depart-

ment in writing when the deficiencies, if any, have been corrected. Following review of the hospital facility's report, the Division of Health Facilities Evaluation and Licensing 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 Licensing and Certification 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 is not assignable or transferable and shall be immediately void if the facility ceases to operate or if its ownership changes.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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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 is not assignable or transferable and shall be immediately void if a hospital ceases to operate or its ownership changes. A hospital shall notify the Department of any change in the ownership form or controlling interests affecting hospital governance. The Department shall determine in accordance with N.J.A.C. 8:33–3.3 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-2.6 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

- (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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-2.12 Mandatory services in general 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.

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.

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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 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)—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 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 shall enter an explanation in the patient's medical record;
- 8. To refuse medication and treatment after possible consequences of this decision have been explained in language the patient understands, except in life-threatening situations and instances when medication or treatment is required by law;
- 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

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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; and

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Native language and distribution requirements added at (a)27. Petition for Rulemaking: Petition from N.J. Hospital Assoc. See: 24 N.J.R. 4131(a), 24 N.J.R. 4290(a), 25 N.J.R. 4676(b). Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Cross References

Regional Maternal and Child Health Consortia, compliance with patient confidentiality requirements in this section, see N.J.A.C. 8:33C-2.4.

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.

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Amended by R.1992 d.132, effective March 16, 1992. See: 23 N.J.R. 3256(a), 24 N.J.R. 942(a).

Text added on multidisciplinary committee and community education on advance directives at (h) and (j); on declaration of death at (k). Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Administrative Change. See: 27 N.J.R. 1615(a).

Law Review and Journal Commentaries

Disputing Advance Care Directives, Robert J. Romano, Jr., 132 N.J.L.J. No. 15, 516 (1992).

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

- (a) The hospital shall have written policies, procedures and bylaws that are reviewed annually, revised 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 lifesustaining 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.
- (1) 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".

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text added at (n) and (o) regarding smoking. Amended by R.1992 d.132, effective March 16, 1992.

See: 23 N.J.R. 3256(a), 24 N.J.R. 942(a).

Text added at (a)4–12 and (b)7 on advance directives. Petition for Rulemaking: Petition from N.J. Hospital Assoc. See: 24 N.J.R. 4131(a), 24 N.J.R. 4290(a), 25 N.J.R. 4676(b).

Administrative Change. See: 27 N.J.R. 1615(a). Administrative Correction.

See: 27 N.J.R. 2215(a).

Rewrote and relettered (l) to (q) as (l) and (m).

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 fulltime 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

National Organ Procurement and Transplantation Network added.

8:43G-5.4 (Reserved)

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 maintain 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 hospital shall have a system to link patients with clergy or spiritual counselors, upon request.
- (e) The hospital shall develop a system for organ donation in accordance with N.J.S.A. 26:6-57 et seq.
 - 1. The hospital shall have the process of organ donation explained to the families of selected critically ill patients by a person who has received training from the hospital in organ donation issues.
 - 2. The hospital shall provide counseling regarding anatomical gifts for families of those patients suitable for organ or tissue donation in which death appears to be imminent.
 - 3. 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.
- (f) 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 Rd, Suite 220A, McLean, VA 22101 (703–827–9582).
- (g) 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.

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

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text on CPR staff added at (i).

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.

New Rule, R.1991 d.450, effective August 19, 1991 (operative October 15, 1991). See: 22 N.J.R. 3469(a), 23 N.J.R. 2526(a).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Reference to Subchapter 4 added.

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. 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.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Annual requirement added at (a); identification and reporting of abuse victims added at (b)6.

Amended by R.1992 d.132, effective March 16, 1992.

See: 23 N.J.R. 3256(a), 24 N.J.R. 942(a). Text added at (b)7 on advance directives.

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.

Emergency New Rule, R.1993 d.138, effective March 2, 1993 (expired May 1, 1993).

See: 25 N.J.R. 1295(a).

Continuity of funding to consortia specified at (c).

New Rule, R.1993 d.229, effective May 17, 1993.

See: 25 N.J.R. 792(a), 25 N.J.R. 1969(a).

Adoption of concurrent proposal by R.1993 d.236, effective April 29, 1993 (Readoption of emergency amendment) and June 7, 1993 (adoption of amendment).

See: 25 N.J.R. 1295(a), 25 N.J.R. 2555(a). Amended by R.1993 d.286, effective June 7, 1993.

See: 25 N.J.R. 1117(a), 25 N.J.R. 2554(a).

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 repri-
- (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

CN 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 Immunode-

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ficiency 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Guideline references specified at (c).

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 bloodborne 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 CN 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 quality assurance methods

There shall be a program of quality assurance for occupational health that is integrated into the hospital quality assurance 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (f) on communication with receiving facilities.

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (b) regarding additional supplies of blood.

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 outpatient 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.

"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 1972.

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

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

"Conduction anesthesia" means the administration of anesthetic agents to interrupt nerve impulses without loss of consciousness. Major conduction blocks include regional nerve blocks (epidural, caudal, and spinal anesthesia). Minor conduction blocks include local infiltration, local nerve blocks, and nerve blocks by direct pressure and refrigeration.

"Conscious sedation" means the administration of drugs to obtund, or dull or reduce the intensity of, pain and awareness without the loss of defensive reflexes.

"Credentialed" means having been granted privileges by the hospital to provide specified anesthesia services, such as administration or supervision of one or more types of anesthetic agents or procedures. "Deep sedation" means the administration of drugs which results in some loss of defensive reflexes; the patient, however, remains arousable by strong stimulation.

"Defensive reflexes" means the ability of an individual to counteract noxious events, especially to defend the breathing passages against foreign material.

"General anesthesia" means the administration of drugs which cause loss of consciousness, that is, complete unawareness of routine surroundings. During general anesthesia, the patient cannot make meaningful responses to even the strongest stimulation.

"Local anesthetic" means an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

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

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

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

"Pain management" means the administration of pharmacologic agents or drugs by any route for the purpose of alleviating acute or chronic pain. Administration of such agents or drugs shall be considered pain management only if it occurs in the absence of any invasive, operative, or manipulative procedure, and if the patient maintains consciousness and defensive reflexes.

"Regional anesthesia" means a major conduction block such as epidural, caudal, and spinal anesthesia.

"Special procedure" means patient care which requires entering the body with instruments in a potentially painful manner. Examples are: Endoscopy (diagnostic and surgical), oral surgery, radiologic procedures, or emergency procedures.

"Special procedure room" means the specially equipped hospital location in which special procedures are performed.

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

New Rule, R.1991 d.451, effective August 19, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Prior text of section recodified to 8:43G-6.2 Anesthesia services policies and procedures.

Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-6.2 Anesthesia services policies and procedures

- (a) Anesthesia services shall be controlled by written policies and procedures that are reviewed annually, revised as needed, implemented, and followed. These policies and procedures shall include at least:
 - 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
 - 4. Preanesthesia evaluation, patient preparation and intraoperative management.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.1.

Case Notes

Hospital required to provide an anesthesiology department, a physician department director and sufficient personnel for emergency needs; exclusive contract for anesthesiological services reasonable, not violative of public policy or antitrust law. Belmar v. Cipolla, 96 N.J. 199, 475 A.2d 533 (1984).

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

- (d) All anesthetic agents, except those utilized for conscious sedation or as minor conduction blocks, shall be administered and monitored only by the following:
 - 1. An anesthesiologist;
 - 2. Under the supervision of an anesthesiologist:
 - i. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification; or
 - ii. A physician resident, a 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 physician who has been credentialed in accordance with medical staff bylaws to administer or supervise the administration of anesthesia, a certified registered nurse anesthetist who holds a current certification under a program governed or approved by the AANA; or
- 4. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.
- (e) The administration and monitoring of any anesthesia, except those agents utilized for conscious sedation or minor conduction blocks, shall be provided by an individual who is continuously present and separate from the individual who is performing the procedure.
- (f) The supervision of any anesthesia, except those agents utilized for conscious sedation or minor conduction blocks, shall be provided by a physician who is immediately available. The supervising physician may concurrently be responsible for patient care if he or she is available to attend to supervisory duties without jeopardizing the life or safety of patients under his or her care. While supervising anesthesia personnel, the supervising physician shall not perform surgery, except minor surgery as defined by medical staff policy, or administer anesthesia to patients under his or her direct care.
- (g) Anesthetic agents used for conscious sedation shall be administered only by the following:
 - 1. A physician who has been credentialed in accordance with medical staff bylaws to administer anesthetic agents used for conscious sedation; or
 - 2. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise anesthetic agents used for conscious sedation and who is immediately available:

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i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA);

- ii. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the AANA, provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification; or
- iii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or
- iv. For a supplemental dose or doses after administration of the initial dose by a credentialed physician who remains continuously in the procedure room, a registered nurse who is trained and experienced in the use of anesthetic agents; or
- 3. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.
- (h) 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 procedure. This individual shall be one of the following:
 - 1. One of the personnel identified in (g) above;
 - 2. A registered professional nurse who is certified in basic cardiac life support and who has training and experience in the use of monitoring devices; or
 - 3. For bronchoscopic procedures only, a licensed respiratory care practitioner.
- (i) Minor conduction blocks shall be administered only by one of the following:
 - 1. A physician who has been credentialed in accordance with medical staff bylaws to administer minor conduction blocks;
 - 2. Under the supervision of a physician who has been credentialed in accordance with medical staff bylaws to administer or supervise minor conduction blocks and who is immediately available:
 - i. A certified registered nurse anesthetist who holds a current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA);

- ii. A registered nurse anesthetist who is a qualified candidate for certification under a program governed or approved by the AANA, provided that no national examination for such certification has been administered since the nurse became a qualified candidate for certification; or
- iii. A physician resident, a dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or
- 3. For dental cases only, a dentist who has successfully completed a nationally approved graduate medical education program in anesthesiology or oral and maxillofacial surgery.
- (j) Minor conduction blocks shall be monitored continuously by medical or licensed nursing personnel.
- (k) Provision shall be made for remote monitoring of the patient if radiation or another direct hazard necessitates the removal of personnel.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.2. Deleted old (c) through (g). Added new (c) through (k).

Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Administrative Correction. See: 27 N.J.R. 1800(a).

8:43G-6.4 Anesthesiologist availability

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

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.3.

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.
- (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) 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 and after the patient's discharge from the postanesthesia care unit.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.4.

In (a), added "physician administering or supervising administration of anesthesia".

In (c), stylistic revisions. Deleted old (d) and (e).

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

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.5.

In (a), added "or equivalent". In (d), added "a reduction in oxygen pressure". In (j), added "written" and deleted "when technical feasible". Deleted old (k).

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 to be 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 maintained for each machine and contained in the patient's anesthesia record. The record may consist of a single phrase or check mark in a box on a form.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.6.

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 regional anesthesia shall be continuously monitored.
- (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.
- (h) The capacity for invasive monitoring of arterial pressure shall exist within the operating suite.
- (i) 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.
- (j) 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.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.7. In (c), added "general or regional". In (d), deleted "all anesthesia, including intravenous, when technically feasible" and added "general anesthesia, regional anesthesia and conscious sedation unless monitoring not clinically feasible". In (e), deleted "when technically feasible" and added "unless monitoring not clinically feasible". In (f), added "regional anesthesia or conscious sedation". In (j), deleted "within the operating suite" and added "in any anesthetizing location in which patients receive general or regional anesthesia". Deleted old (k).

8:43G-6.9 Anesthesia staff education and training

- (a) Requirements for the anesthesia education program shall be as provided in N.J.A.C. 8:43G-5.9.
- (b) Staff education programs and training sessions shall include patient safety and the inspection and use of equipment.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.8. Added new (a).

8:43G-6.10 Anesthesia quality assurance methods

(a) There shall be a program of quality assurance for anesthesia services that is integrated into the hospital quality assurance program and includes routinely 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) Quality assurance shall include morbidity and mortality conferences.
- (c) The hospital shall notify the Division of Health Facilities Evaluation and Licensing, New Jersey State Department of Health by telephone at (609) 588–7727 or (800) 792–9770 within 24 hours, and in writing within 30 days, of all deaths in anesthetizing locations and unexpected intraoperative or postoperative events or outcomes related to anesthesia.
 - 1. The written report shall be submitted on the form entitled "Confidential Report of Anesthesia-Related Incident" (HFE-5), available from the Department of Health, and shall include:
 - i. All deaths in anesthetizing locations, except those in which the patient expired prior to administration of anesthesia; and
 - ii. All unexpected severe intraoperative or postoperative untoward events or outcomes related to anesthesia.
 - 2. Records of such reports and telephone calls shall be made available only to Department of Health personnel for official purposes and, for each report, to the specific facility to which the report pertains.

Amended by R.1991 d.451, effective August 19, 1991, operative October 15, 1991.

See: 22 N.J.R. 3470(a), 23 N.J.R. 2527(a).

Recodified from section 6.9. In (c), changed report submission requirements.

Petition for Rulemaking.

See: 25 N.J.R. 3867(b), 25 N.J.R. 4337(b), 25 N.J.R. 4961(d).

SUBCHAPTER 7. CARDIAC

8:43G-7.1 Scope

The standards set forth in this subchapter shall apply only to separate, designated units or services for cardiac surgery and cardiac catheterization.

8:43G-7.2 Cardiac surgery policies and procedures

- (a) At least 250 open-heart operations shall be performed in each dedicated cardiac operating room per year excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-2.3(a)1, 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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 first 24 hours of the patient's stay in the cardiovascular surgical intensive care service or recovery room.
- (b) For patients who remain in the cardiovascular surgical intensive care service or recovery room after 24 hours, there shall be at least a ratio of one registered professional nurse to two such patients.
- (c) 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.
- (d) 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.

- (e) 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.
- (f) 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.
- (g) 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.
- (h) 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.
- (i) 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Qualifications for cardiac surgery anesthesiologist specified at (c).

Cross References

Cardiac surgery centers, personnel to meet requirements of this section, see N.J.A.C. 8:33E-2.4.

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.

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8:43G-7.8

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 quality assurance methods

- (a) There shall be a program of quality assurance for all cardiac 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 quality assurance 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-1.2(b).
- (c) The cardiac catheterization laboratory shall have written policies and procedures that are reviewed annually, revised as needed and implemented. 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 cardiovascular disease, and who has completed at least one year of additional training or experience in cardiac catheterization.
- (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. The hospital shall determine policy requiring the minimum number of annual procedures that a physician must perform.
- (d) The circulating nurse in the cardiac catheterization laboratory shall be certified in basic cardiac life support.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Qualifications for cardiac surgery primary operator specified at (b).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Staffing requirements revised.

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.
- (1) 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:
 - 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 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Reference to elective surgery deleted at (a).

8:43G-7.23 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) The hospital shall determine policy requiring the minimum number of annual procedures that a physician must perform.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Qualifications for PCTA primary operator specified at (a).

8:43G-7.24 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.

Amended by R.1992 d.72, effective February 18, 1992. See; 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Physician and scrub nurse added.

8:43G-7.25 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-7.26 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Qualifications for primary operator specified at (a).

8:43G-7.27 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text on EPS staff time and availability recodified from 7.28; physician and scrub nurse added.

8:43G-7.28 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text on EPS and staff time and availability recodified to 7.27; new rule on board eligibility status added.

8:43G-7.29 Pediatric cardiac services standards; scope

In addition to the standards in N.J.A.C. 8:43G-7.1 through 7.28 for adult cardiac services, the following standards in N.J.A.C. 8:43G-7.30 through 7.40 shall apply to separate, designated units or services for pediatric cardiac diagnostic services and pediatric surgical centers.

8:43G-7.30 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-7.31 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-7.32 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.

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- (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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text at (a) added.

8:43G-7.33 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Old text deleted; new requirements added.

8:43G-7.34 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;

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- Cardiopulmonary resuscitation;
- 4. Arrhythmia detection and treatment; and

5. Intra-aortic balloon-assisted circulation.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text at (a) added.

8:43G-7.35 Pediatric cardiac surgery quality assurance methods

- (a) There shall be a program of quality assurance for all pediatric cardiac 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 quality assurance program for pediatric cardiac 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-7.36 (Reserved)

8:43G-7.37 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).

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Old text at (b) deleted; new requirements added.

8:43G-7.38 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.

8:43G-7.39 Pediatric cardiac catheterization quality assurance 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-7.40 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.

New Rule, R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

SUBCHAPTER 8. CENTRAL SUPPLY

8:43G-8.1 Central supply policies and procedures

- (a) The hospital's central supply service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies and procedures shall be approved by the hospital's infection control committee.
- (b) Policies and procedures for central supply shall include at least decontamination and sterile 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 supply cleaning and sterilization policies and procedures.
- (d) Manufacturers' recommendations for equipment use, testing, and cleaning shall be readily available in central supply services and in the department where the equipment is used.

8:43G-8.2 Central supply staff qualifications

- (a) There shall be a full-time director or supervisor of central supply services.
- (b) By January 1, 1991, the director or supervisor of central supply shall have received a certificate for completing a central service training course recognized by the Department of Health.

8:43G-8.3 (Reserved)

8:43G-8.4 Central supply patient services

- (a) Entrance to the central supply 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.
- (b) All reusable patient care items shall be reprocessed according to manufacturers' recommendations.
- (c) There shall be a preventive maintenance program for all patient care equipment processed by central supply that includes performance verification records. Preventive maintenance shall be documented.
- (d) All patient care equipment shall be cleaned, disinfected, or sterilized, according to the use of the item.
- (e) Shelf life of packaged sterile items shall be determined and indicated on the items according to central

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supply sterilization policies and procedures which follow guidelines recommended by the Association for the Advancement of Medical Instrumentation (AAMI) as outlined in "Good Hospital Practice: Steam Sterilization and Sterility Assurance," incorporated herein by reference.

(f) Single-use items shall be reused or reprocessed only if the manufacturer recommends reuse or reprocessing, or if the hospital has scientific validation of the safety of reprocessing and reuse of the item. Procedures for reprocessing and reuse shall conform with these recommendations or validation studies.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). AAMI standard incorporated by reference.

8:43G-8.5 (Reserved)

8:43G-8.6 Central supply space and environment

- (a) Sterile supplies shall be processed, packaged, rotated, distributed, stored, and dated in such a way as to ensure the integrity and sterility of the sterile item.
- (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.
- (e) An area shall be designated for central supply employees to change their clothing and store personal items.

8:43G-8.7 Central supply supplies and equipment

- (a) An illuminated worktable shall be provided to examine linen used for wrapping sterile supplies for tears, pinholes, and other defects.
- (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' recommendations or according to policy established by the hospital's infection control committee.
- (c) Scopes and all channels that enter non-sterile areas of the body shall be given high level disinfection after each use according to the manufacturers' recommendations or according to hospital policy.
- (d) Accessories to scopes shall be sterilized or processed according to manufacturers' recommendations after each use.
- (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 supply policies and procedures.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text on sterilization procedures added at (c) and (d).

8:43G-8.8 (Reserved)

8:43G-8.9 Central supply staff education and training

- (a) Requirements for the central supply education program shall be as provided in N.J.A.C. 8:43G-5.9.
- (b) All new central supply service employees shall receive on-the-job training on practices and equipment unique to the hospital.

8:43G-8.10 Central supply quality assurance methods

There shall be a program of quality assurance for central supply 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, 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 sterilizer processed in an open position.
- (b) Before they are sterilizer processed, all instruments and equipment shall be visually inspected for cracks, pitting, rust, or any condition that would impede cleaning.
 - (c) Sterilizers in use shall be kept clean.
- (d) Sterilizer drains shall be flushed at least weekly, unless otherwise specified by the manufacturer.
 - (e) Sterilizer door gaskets shall provide effective sealing.
- (f) 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 current edition of the Centers for Disease Control "Methods for Assuring Adequate Processing and Safe Use of Medical Devices";
 - 2. The Association for the Advancement of Medical Instrumentation, (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance;" and
 - 3. The Association for the Advancement of Medical Instrumentation, (AAMI) requirements, "Good Hospital Practice: Steam Sterilization Using the Unwrapped Method (Flash Sterilization)."

(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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Standards listed at (f)1-3 incorporated by reference.

8:43G-8.12 Sterilizer space and environment

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

8:43G-8.13 Sterilizer supplies and equipment

- (a) All sterilizers shall be operated and maintained in accordance with the manufacturers' instructions.
- (b) An indicating thermometer, accurate to three degrees Fahrenheit, shall be located in all ethylene oxide aeration equipment.
- (c) At the completion of each sterilization load, the time, temperature, and pressure readings shall be checked and verified.
- (d) Double wrapped muslin/paper wrappers shall use an internal and external chemical indicator to monitor every package sterilized. Peel packaging shall have an internal indicator.
- (e) The following equipment tests and monitoring shall be performed as specified and records, including load number, contents of the load, and expiration date, shall be maintained for at least one full year:
 - 1. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer;
 - 2. Biological monitoring with live spores shall be performed at least daily on each ethylene oxide sterilizer and following repair or breakdown of the ethylene oxide sterilizer;
 - 3. For steam sterilizers used to sterilize instruments, biological monitoring with live spores shall be performed weekly for each steam autoclave and following repair or breakdown of the steam sterilizer; and
 - 4. A biological monitor shall be used with each load containing implantable or intravascular items. Implantables shall not be used until the negative biological test is received.
- (f) In the event of positive biological test results on a sterilizer, effective corrective action shall be taken, including retesting and recall if indicated.

(g) There shall be an established recall system in effect.

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 annually, revised 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;

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- 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Qualified supervision to be defined by the hospital and the nursing school.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text on access to lab services deleted at (b).

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;
 - 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 end-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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Supplies to be accessible, not necessarily at bedside.

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 quality assurance methods

- (a) There shall be a program of quality assurance for the critical care service 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 assurance 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) Quality assurance 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text at (b) added on dedicated intermediate care beds. Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-9.20 Intermediate care policies and procedures

- (a) The intermediate care service shall have written policies and procedures that are reviewed annually, revised as necessary, 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.

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8:43G-9.24 Intermediate care quality assurance methods

- (a) There shall be a program of quality assurance for the intermediate care service 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 assurance 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 annually, revised 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic changes at (b).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Duties to be matched to education, training and competence.

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.
- (1) 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 quality assurance methods

- (a) There shall be a program of quality assurance for dietary 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 action based on these 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 at an early stage of the patient's hospitalization. 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.

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(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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Documentation requirements added at (b) and (g).

8:43G-11.6 Discharge planning quality assurance methods

- (a) There shall be a program of quality assurance for discharge planning 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. 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

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 hospital. Special 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 that are reviewed annually, revised as needed, and implemented.
- (b) There shall be a transfer protocol that governs interhospital transfers of patients in need of specialized care not provided in the hospital.
- (c) 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.

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

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Inability to communicate specified at (d).

Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-12.3 Emergency department staff qualifications

- (a) 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 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.
- (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 be certified in Advanced Cardiac Life Support and either Advanced Pediatric Life Support or Pediatric Advanced Life Support within 12 months of initial assignment. Physicians who are board certified in emergency medicine shall be exempt from this requirement.
- (c) 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 be certified in Advanced Trauma Life Support within 12 months of initial assignment. Physicians who are board certified in emergency medicine shall be exempt from this requirement.

(d) The emergency department shall be staffed at all times by at least one professional registered nurse who is certified in Advanced Cardiac Life Support.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Clinical experience requirements added to (a)3 and (c). Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-12.4 (Reserved)

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(a) 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. On-call physicians shall be able to arrive and shall arrive within 30 minutes after being summoned for a critical case, under normal transportation conditions.
- (c) The emergency department shall be staffed at all times by a minimum of one registered professional nurse. The hospital shall have in place a protocol to increase nurse staffing based on volume and acuity.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Case Notes

Care and treatment for the needy sick. Perth Amboy Gen. Hosp. v. Middlesex Freeholders, 158 N.J.Super 556 (Law Div.1978). Att'y Gen.Form Op. 1977–No. 15.

Requirement of a 24-hour licensed physical coverage in emergency department. In re Kessler Memorial Hospital, 154 N.J.Super. 147 (App.Div.1977), rev'd 78 N.J. 564 (1979).

8:43G-12.6 (Reserved)

8:43G-12.7 Emergency department patient services

- (a) All patients shall initially be assigned clinical priority for treatment by a registered professional nurse or physician upon arrival in the emergency department.
- (b) Treatment for life-threatening emergencies shall be initiated immediately.
- (c) No patient, after being admitted to the emergency department, shall be discharged to home or another facility without being seen and evaluated by an attending or emergency department physician.
- (d) All patients who have been admitted to the emergency department shall receive at least initial evaluation by an emergency or attending physician within four hours of arrival in the emergency department.

- (e) 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 a physician exceeds four hours.
- (f) 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.
- (g) 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.
- (h) The hospital shall maintain documentation in all cases in which patients are retained for more than 12 hours in the emergency department.
- (i) No admitted patient 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.
- (j) A registry of emergency department admissions shall be maintained that includes the patient name and at least:
 - 1. Medical record number;
 - 2. Date and time arrived;
 - Time discharged;
 - 4. Name of treating physician;
 - 5. Chief complaint and/or medical diagnosis; and
 - 6. Disposition of the patient.
- (k) Upon discharge home from the emergency department, 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.

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- (1) 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.
- (m) 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.
- (n) 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.
- (o) 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;
 - Allergies;
 - 3. Medications used before admission to the emergency department;
 - 4. Immunizations when relevant;
 - 5. Timed vital signs;
 - 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; and

- 12. Last menstrual period, if relevant.
- (p) 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.
- (q) 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.
- (r) 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.
- (s) 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.
- (t) Radiology services for emergency needs shall be available to the emergency department 24 hours a day.
- (u) Clinical laboratory services for emergency needs shall be available to the emergency department 24 hours a day.
- (v) 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).
- (w) Security personnel shall be available to the emergency department when needed.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

"Hospital" changed to "health care facility" at (m); documentation requirements added.

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 equipment to meet the medical needs of patients of all ages.
- (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 functional two-way communications system 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text on domestic violence and disabled adults added at (b).

8:43G-12.11 Emergency department quality assurance methods

- (a) There shall be a program of quality assurance for the emergency department 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 assurance program shall include periodic collection of emergency department data in at least the following areas:
 - 1. Waiting time;
 - 2. Appropriateness of transfers;
 - 3. Provision of written instructions;
 - 4. Timeliness of diagnostic studies;
 - 5. Appropriateness of treatment rendered;
 - 6. Mortality; and
 - 7. Care of patients who are retained in the emergency department for long periods of time.
- (c) Quality assurance shall include review of selected medical charts.
- (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.

SUBCHAPTER 13. HOUSEKEEPING AND LAUNDRY

8:43G-13.1 Housekeeping policies and procedures

- (a) The housekeeping and service shall have written policies and procedures that are reviewed annually, 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 cleanliness for all equipment, structures, areas, and systems within its scope of responsibility.
- (c) There shall be a list available at all times of all cleaning and disinfecting agents used in the hospital together with a list of their antidotes.
- (d) Records of all pesticides and herbicides used at the hospital shall be maintained on-site, together with a description of their antidotes.
- (e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, including agents that have been repackaged from a bulk source.

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 cabinets, 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.
 - (d) Floors shall be kept clean.
- (e) Hard surfaced floors shall be coated with a slipresistant 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.
- (1) 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, measured, and used correctly and according to manufacturers' 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 condition 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) Buildings and grounds shall be inspected periodically by the director of housekeeping or a designee and maintained in a clean and safe condition.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Fly strips prohibited in patient care 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 cleanser, sanitary towels, and waste receptacles or hand-drying machines shall be provided at each hand-washing unit. Hand cleanser 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 separate from other supplies and in enclosed areas.
- (e) Cleaning agents used in the hospital shall be approved by the housekeeping service and the infection control committee.

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 assurance methods

- (a) There shall be a program of quality assurance for housekeeping that is coordinated with the hospital quality assurance 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.
- (b) Hospitals that contract with a commercial housekeeping service shall use quality assurance 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 annually, revised as needed, implemented, and followed, and which include at least a policy that identifies special handling practices for soiled laundry.
- (b) Contaminated laundry shall be specially handled according to the hospital's written protocol, which is approved by the infection control committee and the director of the laundry service.

8:43G-13.10 Laundry staff qualifications

There shall be a designated director or supervisor of laundry with specialized training or education in institutional laundry service.

8:43G-13.11 Laundry patient services

- (a) All soiled 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.

8:43G-13.12 Laundry space and environment

- (a) Soiled laundry shall be stored in containers provided for it in a clean, ventilated, vermin-proof and vermin-free area, separate from other supplies. It shall be collected from the storage area regularly so that it does not overflow or accumulate beyond the capacity of the storage containers.
- (b) Soiled laundry shall be stored, sorted, rinsed, and laundered only in areas specifically designated for those purposes.
 - (c) If a laundry chute is used, it shall be kept locked.
- (d) If a laundry chute is used, it shall be maintained in good repair and cleaned, and there shall be no build-up of visible soil.
 - (e) Laundry chutes shall empty into an enclosed room.
- (f) If the 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 a supply of sheets, pillowcases, drawsheets, blankets, towels, and washcloths that is at least three times the number of occupied beds.
- (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 at least the following:
 - 1. pH;
 - 2. Unsafe objects found;
 - 3. Linen supply; and
 - 4. Stained linens.
- (d) 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 is 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Bacterial monitoring deleted at (c)1.

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 quality assurance methods

- (a) There shall be a program of quality assurance for the laundry service that is coordinated with the hospital quality assurance program and includes regularly collecting and analyzing data to help identify problems and their extent, recommending, implementing, and monitoring corrective actions on the basis of these data.
- (b) Hospitals that contract with a commercial laundry service shall use quality assurance measures to ensure that the standards of N.J.A.C. 8:43G-13.9 through this section are met.

SUBCHAPTER 14. INFECTION CONTROL AND SANITATION

8:43G-14.1 Infection control structural organization

(a) There shall be a hospital infection control committee that includes representatives from at least: infection control, medical staff, nursing service, administration, clinical laboratory, respiratory care service, surgery, and the employee health service. The committee shall receive formal advice from all other services upon its request.

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8:43G-14.1 DEPT. OF HEALTH

(b) The infection control committee shall direct and assure compliance with the infection control program, including at least the following:

- 1. Formulating a system for identifying and monitoring nosocomial infections that is at least equivalent to the Centers for Disease Control "Definitions for Nosocomial Infections, 1988", PB88–187117, and CDC Guidelines for Isolation Precautions in Hospitals incorporated herein by reference.
- 2. Developing and implementing a system of infection control and isolation procedures, including Universal Precautions, using at least criteria which meet or exceed the criteria established by the Centers for Disease Control and Occupational Safety and Health Administration publication, "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HVB) and Human Immunodeficiency Virus (HIV)", OSHA Instruction CPL 2–2.44A, August 15, 1988 or revised or later editions, 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;
- 4. Instituting control measures or studies when an infection control problem is identified;
- 5. Reviewing, on at least an annual basis, the hospital's policies and procedures related to isolation, aseptic technique, employee health, staff training, antibiotic susceptibility and trends, the prevention of infection, and general improvement of patient care; and
- 6. 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.

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

(c) The infection control committee shall share information, including problems, data, and relevant recommendations, with at least the quality assurance program, nursing service, administration, and the medical staff, and shall ensure that corrective actions are taken.

- (d) The infection control committee shall meet at least once every two months.
- (e) The infection control practitioner shall participate in the development of all hospital policies and procedures related to infection control.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Respiratory care added at (a); nosocomial infection standard incorporated by reference.

8:43G-14.2 (Reserved)

8:43G-14.3 Infection control staff qualifications

The infection control practitioner shall have education or training in surveillance, prevention, and control of nosocomial infections.

8:43G-14.4 (Reserved)

8:43G-14.5 Infection control staff time and availability

- (a) There shall be an infection control practitioner who is 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 practitioner to every 250 occupied beds, but in no case less than one half full-time equivalent, as recommended by the Centers for Disease Control, in "The Efficacy of Infection Surveillance and Control Programs in Preventing Nosocomial Infection in U.S. Hospitals."

8:43G-14.6 Infection control patient services

- (a) The hospital shall comply with all Category 1 measures of the following Centers for Disease Control current publications, incorporated herein by reference, unless the infection control committee makes a documented exception for a specific guideline:
 - 1. Guidelines for Prevention of Catheter-Associated Urinary Tract Infections;
 - 2. Guidelines for Prevention of Intravascular Infections;
 - 3. Guidelines for Prevention of Surgical Wound Infections:
 - 4. Guidelines for Prevention and Control of Nosocomial Pneumonia; and
 - Guidelines for Handwashing and Hospital Environmental Control.

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 practitioner shall coordinate educational programs to address specific problems, as recommended by the Centers for Disease Control, or at least annually for staff in all patient care areas and services.
- (c) Orientation for all new employees shall include infection control practices for the employee's specific area of service and the rationale for the practices.

8:43G-14.8 Infection control quality assurance methods

The infection control practitioner shall develop and implement a program of quality assurance that is integrated into the hospital quality assurance 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 committee shall supervise these quality assurance activities.

8:43G-14.9 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.

NOTE: The Safe Drinking Water Act and rules can be obtained from:

The Department of Environmental Protection Bureau of Potable Water CN 209 Trenton, NJ 08625

(b) Hot running water (between 95 and 110 degrees Fahrenheit) and cold running water shall be provided in patient care areas.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Patient care water temperature redefined.

8:43G-14.10 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 Department of Envi-

ronmental 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-14.11 Sanitation quality assurance 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 Department of Environmental Protection. Records of the sampling and monitoring shall be maintained.

8:43G-14.12 Regulated medical waste policies and procedures

- (a) The hospital shall develop and implement and the infection control committee shall review, approve, and audit written policies and procedures for collection, storage, handling, and disposal 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-14.13 Solid waste policies and procedures

The hospital shall develop and implement and the infection control committee shall review, approve, and audit written policies and procedures for collection, storage, handling, and disposal of all solid waste that is not regulated medical waste.

8:43G-14.14 Solid waste patient services

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

8:43G-14.15 Solid waste space and environment

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

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8:43G-14.16 Solid waste supplies and equipment

- (a) 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.
- (b) Outside storage containers for solid waste shall be kept covered, except those used for corrugated cardboard, recyclables, or construction materials.
- (c) Indoor storage containers for solid waste shall be kept covered when necessary to control odors or other nuisances.

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 annually, revised 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.
- (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 the anesthesiologist. In cases of strictly regional anesthetic where no anesthesiologist is assigned to the case, no preanesthesia, anesthesia or postanesthesia notes by an anesthesiologist are required;
 - 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 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) 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.
- (f) Medical records shall be completed within 30 days of discharge.
- (g) Medical records shall be retained and preserved in accordance with N.J.S.A. 26:8-5 et seq.
- (h) 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.

- (i) 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.
- (j) The patient's death shall be documented in the patient's medical record upon death.
- (k) 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.
- (l) All medical records, including outpatient medical records, shall be organized in a uniform format within each clinical service.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Electronic and fax order requirements specified at (b)1-2; outpatient records included at (c).

Amended by R.1992 d.132, effective March 16, 1992.

See: 23 N.J.R. 3256(a), 24 N.J.R. 942(a).

Text on documentation of advance directives added at (d) and (e). Petition for Rulemaking. See: 25 N.J.R. 3563(d).

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. ("Legally authorized representative" means spouse, immediate next of kin, legal guardian, patient's attorney, or third party insurer where permitted by law.) 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.

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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;
 - ii. A postage charge of actual costs for mailing, not to exceed \$5.00. 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.
- (e) If the patient or the patient's legally authorized representative subsequently requests additional copies of a medical record which has been furnished in accordance with (d) above, the additional copy(s) shall be furnished at a fee based on actual costs, and in no case shall exceed \$1.00 per page.
- (f) The Department shall periodically reevaluate the reasonableness of the fee scale contained in (d) above, and shall report to the Health Care Administration Board on or before July 1, 1993 on the need for amendment.
- (g) 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.
- (h) 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.
- (i) Incidents, including patient injuries and mishaps, shall be fully documented in the patient's record.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Record copying fees and standards specified at (d) through (g).

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 quality assurance methods

- (a) There shall be a quality assurance program for medical records 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) Quality assurance 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 termi-

nated 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.
- (1) 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:

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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.

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Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Notifications of practitioner status change required by (k) to be made in seven days.

Case Notes

Members of medical peer review committees had immunity for actions, recommendations or statements. Bundy v. Sinopoli, 243 N.J.Super. 563, 580 A.2d 1101 (L.1990).

Privilege of self-critical evaluation protects from discovery opinions, criticisms, or evaluations contained within peer review committee files. Bundy v. Sinopoli, 243 N.J.Super. 563, 580 A.2d 1101 (L.1990).

8:43G-16.2 Medical staff policies and procedures

- (a) The medical staff shall have written policies, procedures, and by-laws that are reviewed annually; revised 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).

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Reference changed at (b). Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Case Notes

In action brought by physician challenging termination of staff privileges at hospital, regulation cited to support court's deference to decisions of hospitals to maintain a qualified medical staff. Nanavati v. Burdette Tomlin Memorial Hospital, 107 N.J. 240, 526 A.2d 697 (1987).

All hospital employees subject to regulatory supervision; restrictive staff admission policy invalid as not reasonably in furtherance of legitimate health objective. Desai v. St. Barnabas Medical Center, 103 N.J. 79, 510 A.2d 662 (1986).

Regulations require hospital to appoint organized medical staff responsible to governing board; hospitals must adopt rules concerning procedures for staff membership admission; qualified doctors may not be arbitrarily excluded from staff; exclusive contract for anesthesiological services reasonable, not violative of public policy and not illegal tying arrangement under Antitrust Act. Belmar v. Cipolla, 96 N.J. 199, 475 A.2d 533 (1984).

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 physician 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 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Diagnosis to be provided seven days prior to or 24 hours after admission.

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).

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic change.

8:43G-16.8 Medical staff quality assurance 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) Nurse staffing assignments shall be based on patient acuity levels, determined through patient classification systems which address the needs of the nursing unit.
- (b) There shall be a registered nurse manager for each patient care unit and for surgery, emergency department, and other units, as specified in the hospital organizational plan or policies and procedures.
- (c) The hospital shall have in place an acuity system that has at least the following characteristics:
 - 1. Patients are classified through a factor evaluation or prototype evaluation system, based on clinical assessments of the comprehensive nursing needs of each patient;
 - 2. Acuity assessments are made on a daily basis for patients in each care unit;
 - 3. Acuity assessments are made by registered professional nurses; however, licensed practical nurses may participate in a patient classification system within their scope of practice;
 - 4. The hospital makes staffing decisions based on the daily acuity data, as well as the qualifications of personnel needed to meet the nursing care needs;
 - 5. Licensed nurses shall provide at least 65 percent of the direct patient care hours indicated as needed on inpatient units by the hospital's acuity system to patients on a hospital wide average; and
 - 6. The hospital conducts regular monitoring and review studies of its own acuity system, including indicators of reliability.
- (d) 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.
- (e) 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.

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(f) 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.

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 annually, revised 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 fulltime 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 criteriabased system for evaluating at least annually the performance of each nursing service employee.
- (f) 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.
- (g) 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.
- (b) The hospital shall have written policies and procedures regarding the use of physical restraints that are reviewed annually, revised 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 licensed nursing staff 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 or another designated physician shall be notified immediately and shall respond within one hour. A physician order shall be given if the use of restraints is to continue beyond one hour. The physical and mental condition of the patient shall be evaluated and documented by medical or licensed nursing personnel at least once every two hours. The attending or designated physician shall personally observe and evaluate the patient within 24 hours, and continuation of restraints shall occur only upon written physician orders.
- (e) In all cases, the attending or designated physician shall observe the restrained patient at least once every 24 hours to evaluate any changes in the patient's physical or mental status. The need for continued restraint shall be documented in the patient's record and implemented only by written physician orders, which must be renewed every 24 hours.
- (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 physical and mental 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. Periodic visual observation which is performed with the following frequency:
 - i. Continuously if clinically indicated by the patient's condition; or
 - ii. At least every 15 minutes while the patient's condition is unstable; and
 - iii. Thereafter at least every 30 to 60 minutes based upon an evaluation of the patient's acuity;
- 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;
 - Administration of fluids as required;
 - 3. Toileting as required; and
 - 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.

New Rule, R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

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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 or identifies nursing diagnoses, shall be prepared by a registered professional nurse within 24 hours of admission.
- (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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

See: 23 N.J.R. 2590(a), 24 N.J. Stylistic change.

Amended by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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).

New Rule, R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text at (b) added.

8:43G-18.8 (Reserved)

8:43G-18.9 Nursing care quality assurance methods

There shall be a program of quality assurance for nursing care 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. Issues shall be identified through, at least, incident reports, infection control activities, and patient and staff comments.

SUBCHAPTER 19. OBSTETRICS

Cross References

Community Perinatal Center—Birthing Center, prenatal, postpartum, and newborn care provided as under this section, see N.J.A.C. 8:33C-6.1.

Community Perinatal Center—Intermediate facility, prenatal, post-partum and newborn care as under this section, see N.J.A.C. 8:33C-7.1.

Regional Perinatal Centers and Community Perinatal Centers, compliance with current hospital licensure standards, see N.J.A.C. 8:33C-4.2.

8:43G-19.1 Scope of obstetric standards; definitions

- (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.
- "Administrative nurse coordinator" means a registered professional nurse currently licensed by the New Jersey State Board of Nursing, who has administrative responsibility over the areas of labor and delivery, recovery, newborn nurseries and postpartum and antepartum.

"Clinical nurse coordinator" means a registered professional nurse currently licensed by the New Jersey State Board of Nursing, who has clinical responsibility over the areas of labor and delivery, recovery, newborn nurseries and postpartum and antepartum.

"Community Perinatal Center" 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 and normal newborn patients 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 36 weeks gestation.
- 2. "Intermediate" provides care to complicated 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 1,499 grams and 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 hospital and the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 999 grams and 28 weeks gestation.

"Maternal and child health inpatient services" means labor and delivery, postpartum, newborn care and pediatric services.

"Maternal and Child Health Consortium (MCHC)" means a voluntarily formed non-profit organization, incorporated under Section 501(c)(3) of the United States Internal Revenue Code, consisting of all inpatient, ambulatory perinatal and pediatric care providers and related community organizations in a maternal and child health service

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region, licensed as a central service facility by the Department of Health.

"Maternal and Child Health Service Region" means the perinatal and pediatric service delivery area defined by the concept of cooperative network formation. Contained within each region is at least one Regional Perinatal Center, one Regional Pediatric Center and the balance, Community Perinatal and Pediatric Centers.

"Mechanical ventilatory support" means the application of positive pressure ventilation and oxygen through mechanical devices to include continuous positive airway pressure (CPAP).

"Perinatal clinical nurse specialist" means a registered professional nurse currently licensed by the New Jersey State Board of Nursing with a master's degree in a maternal and child health nursing specialty from an accredited college or university. This individual is responsible for providing hospital and regional professional education and consultation.

"Regional Perinatal Center" means a licensed hospital which is the preferred provider of care to high risk mothers and high risk neonates in the maternal and child health region. Such a facility is responsible for providing consultation, referral, transport and follow-up to the region.

- (c) All hospitals with obstetric services shall, in accordance with N.J.A.C. 8:33C, 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 of a Regional Maternal and Child Health Consortium.
- (d) All Community Perinatal Centers and Regional Perinatal Centers shall provide services in accordance with a letter of agreement approved 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.

(g) All Regional Perinatal Centers shall provide high risk infant follow-up services in accordance with N.J.A.C. 8:33C-8.2(c).

Amended by R.1992 d.347, effective September 8, 1992.

See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a). Definitions added at (b).

Amended by R.1993 d.286, effective June 7, 1993.

See: 25 N.J.R. 1117(a), 25 N.J.R. 2554(a).

8:43G-19.2 Obstetrics policies and procedures

- (a) The obstetric service shall have written policies and procedures that govern and are available in all areas of the obstetric service and are reviewed annually, revised as needed, and implemented. These policies and procedures shall 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) If alternative birthing services are provided, there shall be written criteria for admission.
- (d) On obstetric units where Cesarean sections are performed, all requirements of surgical standards shall apply.

(e) 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text on prenatal record added at (f).

Amended by R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

Text regarding transfer of patients at (e) deleted; subsections recodified.

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) The inpatient obstetric service in hospitals designated as a Community Perinatal Center-Basic shall have a full-time registered professional nurse, with clinical responsibility for all nursing care. This individual may function as the registered nurse manager required at N.J.A.C. 8:43G-17.1(b). The qualifications for this position include the following:
 - 1. A minimum of three years of experience in inpatient obstetric services within the five years immediately preceding the date of appointment; and
 - 2. Educational preparation in maternal-fetal or neonatal nursing, in accordance with hospital policy.
- (c) All health professionals assigned to the post-partum service shall be trained in the care of both mothers and infants.
- (d) The obstetric service in a hospital designated as a Community Perinatal Center-Intermediate or Intensive and Regional Perinatal Centers shall have a registered professional nurse who functions as an administrative nurse coordinator with responsibility for all nursing care. This individual may also function as the registered nurse manager required at N.J.A.C. 8:43G-17.1(b). Additionally, this individual may be assigned clinical responsibility for all nursing care at Community Perinatal Centers-Intermediate. The qualifications for this position include:
 - 1. A minimum of three years of experience in maternal and child health inpatient services within the five years immediately preceding the date of appointment; and
 - 2. A continuing education course in maternal-fetal or neonatal nursing approved by a nationally recognized nurse education accrediting body.
- (e) The obstetric service in a hospital designated as a Community Perinatal Center–Intensive shall have a clinical nurse coordinator who is a registered professional nurse and who has:

- 1. A minimum of five years experience in maternal and child health inpatient services within the seven years immediately preceding the date of appointment. Of the five years minimum experience, at least one year shall have been in a supervisory capacity and one year shall have been in clinical neonatal intensive care; and
- 2. A continuing education course in maternal-fetal or neonatal nursing approved by a nationally recognized nurse education accrediting body.
- (f) The obstetric service in hospitals designated as a Regional Perinatal Center shall have a perinatal clinical nurse specialist who is responsible for intramural 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 five years experience in maternal and child health inpatient services within the seven years immediately preceding the date of appointment. Of the five years minimum experience, two years shall have been in an educational capacity; and
 - 2. Effective October 1, 1993, certification by the National Certification Corporation for the Obstetric, Gynecologic, and Neonatal Nursing Specialties or American Nurses' Association.

Amended by R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

Text added to require recent experience and education; new subsections (d)-(f) added.

8:43G-19.4 Obstetrics staff time and availability

- (a) The obstetric service in hospitals designated as a Community Perinatal Center-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.
- (b) The obstetric service in hospitals designated as a Community Perinatal Center–Intermediate shall be covered at all times by a board eligible or certified obstetrician 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.
- (c) The obstetric service in hospitals designated as a Community Perinatal Center–Intensive shall be covered at all times by a board certified obstetrician, who is present in the hospital or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions.

- (d) The obstetric service in hospitals designated as a Regional Perinatal Center shall be covered at all times by:
 - 1. A board eligible or certified obstetrician who is present in the hospital; and
 - 2. 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.
- (e) The physician in (d)2 above may also fulfill the requirement for physician coverage at (d)1 above during those times in which he or she is present in the hospital.

New Rule, R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

Case Notes

Registered nurse requirement in labor-delivery and obstetrics rooms under former N.J.A.C. 8:43B-8.4. In re: Kessler Memorial Hospital, 154 N.J.Super. 147 (App.Div.1977), reversed 78 N.J. 564, 381 A.2d 44 (1979) dissenting opinion.

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, prevention of infection and disease in infants, hospital policies and procedures regarding visitors, infection control during the hospital stay 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) Anesthesia service shall be available at all times. Anesthesia personnel shall be present in the hospital at all times or available by telephone and able to arrive within 30 minutes of being summoned, under normal transportation conditions.
- (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.
- (f) The medical record for the obstetric patient shall include the prenatal record, documentation of the course of labor, delivery, and the post-partum period and a copy of any vital records filed in accord with N.J.S.A. 26.

(g) Criteria shall be developed in consultation with the dietary department for identifying patients at nutritional risk. Patients determined to be at nutritional risk shall receive dietary counseling.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text on dietary criteria added at (g).

8:43G-19.6 Maternal-fetal transport and neonatal transport

- (a) Maternal transports for maternal management shall only be accepted by a hospital designated as a Regional Perinatal Center. Maternal 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.
- (b) Each Community Perinatal Center shall establish and implement transfer agreements for patients who require a higher level of care for maternal management or delivery than the hospital is designated to provide. This shall be documented in its letter of agreement with the Regional Perinatal Center.
- (c) The Regional Perinatal Center shall develop and implement policies and procedures that establish a 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.
- (d) The hospital shall establish and implement transfer agreements for neonates who require a higher level of care than the hospital is designated to provide. Transfer agreements shall be developed in cooperation with the Maternal and Child Health Consortium, only with hospitals designated as Regional Perinatal Centers or Community Perinatal Centers—Intensive, and in accordance with the Regional Perinatal Plan. 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.
- (e) All infants, regardless of birth weights, who require major surgery or other highly specialized services shall be transported to a Regional Perinatal Center, children's hospital or specialized hospital capable of providing the care.
- (f) All Regional Perinatal Centers and Community Perinatal Center—Intensives which have a letter 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 arrival time for the physicians with pediatric subspecialties identified in (f)3 above.

New Rule, R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

8:43G-19.7 Obstetric space and environment

The obstetric service shall be physically separate from any service not concerned with obstetric care.

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 quality assurance methods

- (a) There shall be a quality assurance program for obstetrics 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 assurance program for obstetrics should include at least: high-risk screening, review of unattended deliveries, transfers to other facilities and return transfers, appropriateness of Cesarean sections, use of oxytoxic drugs, prevention of infections in the nursery, morbidity by birth weight, and mortality by birth weight.

8:43G-19.11 (Reserved)

8:43G-19.12 Labor and delivery policies and procedures

- (a) Restrictions shall be established and posted governing entry into the labor and delivery unit.
- (b) Entry into the surgical area shall be restricted to staff and support persons. Scrub attire shall be required.

8:43G-19.13 Labor and delivery staff time and availability

- (a) There shall be at least one registered professional nurse present whenever a patient is in the 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, or by a licensed nurse-midwife.

- (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) Oxytoxics shall be administered within one hour of examination of the patient by a physician with obstetrical privileges and initiation of electronic fetal monitoring.
- (e) A health professional trained in neonatal resuscitation shall be available within the obstetrics unit for each delivery.
- (f) Effective January 1, 1992, there shall be a health professional certified in neonatal resuscitation immediately available to the newborn service whenever an infant is present.
- (g) A pediatrician or pediatric resident shall be present in the delivery room for all high-risk deliveries.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Physician to examine patient prior to use of oxytoxics; neonatal resuscitation to be available when infant is present.

8:43G-19.14 Labor, delivery, anesthesia and recovery patient services

- (a) A registry of all births or maternity log books shall be maintained in the labor and delivery room and shall include the minimum data set required by the Maternal and Child Care Committee of the New Jersey Medical Society as accepted by the Department of Health.
- (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 or II 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 III, 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).

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (b) on anesthesia; at (c) on recovery.

8:43G-19.15 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (c), requiring policies and procedures.

8:43G-19.16 Postpartum patient services

- (a) The hospital shall provide or arrange for an organized program of postpartum 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.
- (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-19.17 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 shall perform a complete physical examination of the newborn within 24 hours of birth.
- (c) A physician shall perform an examination of the newborn on discharge.
- (d) 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.)
- (e) 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.
- (f) 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 through 112), reporting congenital defects (N.J.S.A.

- 26:8-40.20 et seq.), and completing birth certificates (N.J.S.A. 26:8-28) and death certificates.
- (g) Policies and procedures for screening newborns for high risk factors associated with hearing impairment, in accordance with N.J.S.A. 26:2–101 et seq. shall be as follows.
 - 1. A physician or registered professional nurse shall screen the newborn using the Newborn Hearing Screening Report Form of the New Jersey Hearing Evaluation Council and the Special Child Health Services Program of the Department; and
 - 2. The facility shall send copies of the Newborn Hearing Screening Report Form for all at risk newborns, within one week of the infant's discharge to the Special Child Health Services Program of the Department.
- (h) 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 through 112, 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.
 - (i) 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;

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- 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Details of roster, notification procedure and ophthalmic treatment specified.

8:43G-19.18 Newborn care staff qualifications

- (a) There shall be a physician director of newborn care who is board certified in pediatrics and who is responsible for the direction, provision, and quality of medical care provided.
- (b) The physician director of newborn care shall designate in writing an alternate physician who is a pediatrician to act in his or her absence.
- (c) There shall be a full-time nurse with administrative or clinical responsibility for all nursing care in the newborn nursery who is a registered professional nurse with the equivalent of three years of full-time experience in maternal and child nursing. The nurse with administrative or clinical responsibility for newborn care may also be responsible for nursing on the obstetric service.
- (d) There shall be a health professional trained in infant resuscitation available within the unit at all times.
- (e) Effective January 1, 1992, there shall be a health professional certified in neonatal resuscitation immediately available to the newborn service whenever an infant is present.

(f) A hospital designated as a Regional Perinatal Center shall have a physician director of the neonatal intensive care nursery who is board certified in pediatrics with certification in neonatal medicine.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Neonatal resuscitation to be available when infant is present.

Amended by R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

Subsection (f) added.

8:43G-19.19 Newborn care staff time and availability

- (a) The basic newborn nursery shall be covered at all times by a pediatrician or family practice physician with pediatric privileges, 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.
- (b) The basic newborn nursery shall have a registered professional nurse present whenever an infant is in the newborn nursery. Additional staffing assignments shall be determined by acuity levels appropriate to infants.
- (c) The basic newborn nursery shall have at least one registered professional nurse to every eight infants. However, so long as one registered nurse is on duty as required by (b) above, licensed practical nurses may be used to comply with the nurse:infant ratio requirement.
- (d) 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, 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 shall be present in the hospital whenever an infant is on a ventilator.
- (e) The intermediate nursery shall have at least one registered professional nurse to every four infants. Additional staffing assignments shall be determined by the acuity levels of the infants.
- (f) The neonatal intensive nursery shall be covered at all times by a neonatal fellow or a board eligible or certified pediatrician with training and experience in neonatal medicine, present in the hospital.
- (g) The neonatal intensive nursery 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 infants. Additional staffing assignments shall be determined by the acuity levels of the infants.

Amended by R.1992 d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a).

Nursing and physician coverage specified in (a) and (b); subsections (c)-(h) added.

8:43G-19.20 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) A Community Perinatal Center—Basic may provide care to neonates greater than 2499 grams and 36 weeks gestation. A Community Perinatal Center—Basic may provide care to infants 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 Community Perinatal Centers—Basic and if it has been documented in the medical record that the birth was expected to meet the weight and age criteria. Service restrictions placed on Community Perinatal Centers—Basic include:
 - 1. A Community Perinatal Center—Basic shall not provide mechanical ventilatory support, except for resuscitative measures;
 - 2. A Community Perinatal Center—Basic shall not provide total parenteral nutrition; and
 - 3. A Community Perinatal Center—Basic shall transfer all neonates requiring a higher level of services than permitted to be provided by the facility in accordance with its letter of agreement.
- (c) A Community Perinatal Center—Intermediate may provide care to neonates greater than 1,499 grams and 32 weeks gestation. A Community Perinatal Center—Intermediate may provide care to infants 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 Community Perinatal Center(s)—Intermediate and if it has been documented in the medical record that the birth was expected to meet the weight and age criteria. Service restrictions placed on Community Perinatal Center(s)—Intermediate include:
 - 1. A Community Perinatal Center—Intermediate may provide short term mechanical ventilatory support. In no case shall mechanical ventilatory support exceed 48 hours,

- except in cases where authorization has been received from the neonatologist on-call at the Regional Perinatal Center and the Center has demonstrated 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 shall be obtained on a daily basis and shall be documented in the medical record.
- 2. A Community Perinatal Center—Intermediate shall not provide total parenteral nutrition, except in cases where authorization has been received from the neonatologist on-call at the Regional Perinatal Center. Authorization from the neonatologist on-call at the Regional Perinatal Center shall be obtained on a daily basis and shall be documented in the medical record.
- 3. A Community Perinatal Center—Intermediate shall transfer all neonates requiring a higher level of services than permitted to be provided by the facility in accordance with its letter of agreement.
- (d) A Community Perinatal Center—Intensive may provide care to neonates greater than 999 grams and 28 weeks gestation. A Community Perinatal Center—Intensive may provide care to infants 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 Community Perinatal Center(s)—Intensive and if it has been documented in the medical record that the birth was expected to meet the weight and age criteria. A Community Perinatal Center—Intensive may provide long term ventilatory support and total parenteral nutrition.
- (e) A Regional Perinatal Center may provide long term ventilatory support and total parenteral nutrition.
- (f) 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.
- (g) 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.
- (h) There shall be a system for verifying the identity of mothers and infants whenever an infant is removed from, or returned to, the nursery.
- (i) 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 that accept such documentation before an official birth certificate is issued.

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8:43G-19.20 DEPT. OF HEALTH

Amended by R.1992, d.347, effective September 8, 1992. See: 24 N.J.R. 2045(a), 24 N.J.R. 3165(a). Amended by R.1993 d.286, effective June 7, 1993. See: 25 N.J.R. 1117(a), 25 N.J.R. 2554(a).

8:43G-19.21 Newborn care space and environment

The newborn nursery shall be in a closed unit, physically segregated from other areas.

8:43G-19.22 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Equipment checks deleted at (g).

8:43G-19.23 Scope of nurse midwifery standards

The standards in N.J.A.C. 8:43G–19.24 through 19.29 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–19.26(a) and 19.27.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Exception added.

8:43G-19.24 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-19.25 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-19.26 Nurse-midwifery staff qualifications

- (a) There shall be a licensed 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 licensed by the New Jersey Board of Medical Examiners.

8:43G-19.27 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-19.28 (Reserved)

8:43G-19.29 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-19.30 Scope of obstetric/non-obstetric mix standards

The standards in N.J.A.C. 8:43G-19.31 through 19.33 shall apply to hospitals that place non-obstetric patients on obstetric patient care units. The obstetric/non-obstetric mix program is restricted to admission of female non-obstetric patients.

19:43G-19.31 Obstetric/non-obstetric mix structural organization

- (a) If the hospital mixes obstetric and non-obstetric inpatients on the obstetric unit, there shall be an established obstetric/non-obstetric mix committee that meets at least once a year and includes at least:
 - 1. The medical director of the obstetric service;
 - 2. The nurse with administrative or clinical responsibility for nursing care on the obstetric service;
 - 3. A medical records representative;
 - 4. The operating suite supervisor or representative;
 - 5. An admissions office representative;
 - 6. The infection control practitioner; and
 - 7. A representative of hospital administration.
- (b) The medical director of the obstetric service shall sign and review monthly reports, that include the following:
 - 1. Monthly summaries of the non-obstetric log book and the maternity log book;
 - 2. Review of all non-obstetric patients who are transferred from the obstetric unit, with notes on the reason for transfer, and the results of cultures for those patients transferred for reasons for morbidity or infection;
 - 3. Review of all cases of maternal morbidity and the causes, with notes on the results of cultures; and
 - 4. Review of all cases of infant morbidity and the causes, with notes on the results of cultures.

8:43G-19.32 Obstetric/non-obstetric mix policies and procedures

- (a) If the hospital mixes obstetric and non-obstetric inpatients on the obstetric and newborn unit, it shall have prior written permission from the Department of Health, Division of Health Facilities Evaluation.
- (b) There shall be written policies and procedures for the obstetric/non-obstetric mix program that are reviewed annually by the obstetric/non-obstetric mix committee, revised as needed, and implemented. These policies shall include:
 - 1. Criteria and procedures for admission;
 - 2. Criteria for non-admission; and
 - 3. Protocols for cultures of non-obstetric patients, including the type of cultures, when, and under what circumstances they are performed.
- (c) 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. Patient's age;
 - 2. Dates of hospital admission and discharge;

- 3. Admission and discharge diagnoses;
- 4. Date and type of surgery, if performed, including associated procedures, and name of surgeon;
 - 5. Morbidity and cause, if applicable;
- 6. Destination, date, and reason for transfer to other units of the hospital; and
 - 7. Medical record number.
- (d) An admission check sheet and questionnaire, approved by the New Jersey Department of Health, 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-19.33 Obstetric/non-obstetric mix patient services

- (a) A non-obstetric patient shall be admitted to the obstetric service only if the number of beds left available on the unit for obstetric patients is greater than the average number of deliveries per day for the hospital, as determined by data from quarterly utilization reports.
- (b) No obstetric patient shall be excluded from the obstetric service. A bed shall be made available, when needed by obstetric patients, by the transfer of a non-obstetric patient.
- (c) A non-obstetric patient who is admitted to the obstetric service shall not share a room with an obstetric patient.
- (d) 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. Mental illness;
 - 4. A case of known or suspected infection, as specified in the obstetric policies and procedures;
 - 5. A history of household contacts with staphylococcal infection or other contagious diseases that have occurred within one month prior to admission;
 - 6. Known malignancy requiring extensive surgery or the use of radium;
 - 7. A surgical procedure that is not on a list approved by the obstetric/non-obstetric mix committee;
 - 8. A hemorrhoidectomy or other bowel surgery, with the exception of the excision of small hemorrhoidal tabs;
 - 9. 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

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- 10. Was admitted to a hospital during the two week period prior to admission.
- (e) A non-obstetric patient shall be transferred from the obstetric service if she:
 - 1. Has an oral temperature of 100.4 degrees Fahrenheit or higher on any two successive days, exclusive of the first 24 hours following surgery;
 - 2. Has any sign of infection, including infection discovered at the time of surgery; or
 - 3. Has received perioperative prophylactic antibiotics more than six hours prior to surgery or more than 72 hours following surgery.
- (f) All surgical procedures performed on non-obstetric patients on the obstetric service shall be performed in the operating suite.
- (g) Oral temperature readings shall be taken at least every 12 hours for all non-obstetric patients on the obstetric service.
- (h) The same visitors policy shall apply to both obstetric and non-obstetric patients on the mixed obstetric service.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Patient priority specified at (b).

8:43G-19.34 (Reserved)

8:43G-19.35 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.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.36 Functional areas for newborn care

- (a) Functional areas for newborn care shall be as follows:
 - Resuscitation Area or Room;
 - 2. Admission Observation Area;
 - 3. Normal Newborn Nursery (Level 1);
 - 4. Continuing Care Growing Nursery or Area;
 - 5. Suspect Isolation Nursery;
 - 6. Intermediate Care Nursery (Level II); and
 - 7. Intensive Care Nursery (Level III).

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.37 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 (l) below.
- (b) Each nursery shall be illuminated with ceiling fixtures connected to a rheostat which shall provide a minimum of 25 foot candles to a maximum of 150 foot candles at the body surface of the infant. In addition, each Level III facility shall have a ceiling fixture centered over each patient station connected to an individual rheostat.
- (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 compressed air piped from a central source at 50 to 60 pounds per square inch (psi). Reduction values and mixers shall produce a 21 percent to 100 percent concentration of oxygen at atmospheric pressure for head hoods and 50 to 60 psi for mechanical ventilators.
- (e) Oxygen air and suction systems shall have chime alarms to signal loss of suction or low oxygen and air supply.
- (f) The construction of the nursery shall include acoustic absorption units or other means to keep sound intensity below 75 decibel (db).
- (g) A temperature of 75 degrees Fahrenheit and a relative humidity of 50 percent shall be maintained.
- (h) Wall finishes shall be off white or pale beige in color to minimize distortion of staff's color perception in patient care area.
- (i) An emergency call system shall be provided in each nursery.
- (j) A free-standing handwashing sink shall be provided with foot control and a bowl large and deep enough to prevent splashing. A liquid soap dispenser and disposable towel dispenser shall be provided at each sink.
- (k) Electric outlets shall be supplied by at least two branch circuits of 15 amps each.
- (1) In the entire newborn suite there shall be a total of six air changes per hour, with two of these changes being outside air, and filtration of 25 percent with final filtration of 90 percent before air enters the nursery. Positive pressure shall be maintained.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.38 Staff offices and lounge

There shall be two staff offices and a staff lounge in, or adjacent to, the newborn suite.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.39 Infant formula facilities

- (a) If infant formula is prepared on the hospital site, the following shall be provided:
 - 1. Facilities for washing and sterilizing supplies;
 - 2. A separate room for preparing infant formulas, with direct access from formula room to a nursery or to a nursery workroom; and
 - 3. A separate refrigerator/freezer for the storage of breast milk and formula.
- (b) If a commercially prepared pre-packaged infant formula is used, then a separate clean area shall be provided for the storage of formula. Such storage may be provided in the Nursery Workroom. The preparation area shall have a work counter, a handwashing sink and storage facilities. A separate refrigerator/freezer shall be provided for storage of breast milk.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.40 Neonatal unit soiled utility room

- (a) A soiled utility room shall contain the following:
 - 1. A clinical sink;
 - A work counter;
 - 3. A hand-washing sink foot control;
 - Liquid soap dispensers;
 - 5. A paper towel dispenser; and
- 6. Space for storage of soiled equipment, soiled linen and trash receptacles.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.41 Neonatal unit clean work area or room

- (a) A neonatal unit clean work area or room shall contain:
 - 1. A counter with cabinets;
 - 2. A refrigerator;
 - 3. A handwashing sink with knee control;
 - 4. Liquid soap dispensers;
 - 5. A paper towel dispenser; and
 - 6. Space for storage of clean equipment and clean linen.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.42 Neonatal unit janitor's closet

A neonatal unit janitor's closet shall be provided in the suite and shall contain floor receptor or service sink and storage space for housekeeping equipment and supplies.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.43 Neonatal unit clerical area

There shall be a clerical area near the entrance to the nurseries which shall provide an area for recording. The clerical area shall be designed to allow staff to supervise traffic and to eliminate unwarranted entry into the patient care area. The clerical area shall have telecommunication with all nursery areas and the delivery suite.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.44 Neonatal unit multipurpose rooms

- (a) In Level I facilities, there shall be one multi-purpose room for consultation and conferences.
- (b) In Level II facilities, there shall be two multi-purpose rooms, one for consultation and conferences and one for use as a parent teaching breast feeding room.
- (c) In Level III facilities, there shall be four multi-purpose rooms, as follows:
 - 1. A parent-teaching demonstration room;
 - 2. A consultation conference room;
 - 3. A parent room for breast feeding; and
 - 4. A parent sleeping room with adjoining toilet and shower.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.45 Neonatal unit nursery area

- (a) The normal newborn nursery, continuing care nursery and admission nursery shall be served by a connecting workroom. One workroom may serve several normal newborn nurseries, provided that required services are convenient to each. The workroom shall contain work space with:
 - 1. A counter;
 - A refrigerator;
 - 3. A handwashing sink with foot control; and
 - 4. Storage space.

- (b) 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 unit nursery.
- (c) A scrub gowning area shall be provided for staff and housekeeping personnel at the entrance of each nursery, but separated from the work area. The scrub gowning area shall contain a free standing handwashing sink with foot control 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 for clean gowns;
 - 3. Receptacle for used gowns; and
 - 4. A large wall clock with sweep second hand for timing hand washing.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.46 Neonatal unit resuscitation area

- (a) The resuscitation area shall be part of the delivery room or shall be a separate resuscitation room adjacent to an opening into the delivery room.
 - (b) The resuscitation area shall contain:
 - 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; and
 - 4. A table or flat surface for trays.
- (c) The resuscitation area shall contain a minimum of 40 additional square feet of clear floor area when included as part of the delivery section room.
- (d) If the program requires a separate resuscitation room, it shall contain a minimum of 150 square feet of clear floor
- (e) The neonatal resuscitation area shall have a minimum of:
 - One oxygen outlet;
 - 2. One compressed air outlet; and
 - 3. One suction outlet.
- (f) 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.
- (g) If a separate resuscitation room is provided, the room shall contain a free-standing handwashing sink.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.47 Neonatal admission/observation area

- (a) The admission/observation area shall be near or adjacent to the delivery room and convenient to the postpartum Nursing Unit. One patient station for every 400 annual births shall be provided. There shall be a minimum of two stations in this area. In Level I facilities, the admission/observation area may be located in the newborn nursery or continuing care area, if a separate room is not provided.
- (b) There shall be a minimum of 40 square feet of floor area for each infant station with a minimum of three feet between bassinets.
- (c) One oxygen outlet, one compressed air outlet and two suction outlets shall be provided at each infant station.
- (d) Six single or three duplex electrical outlets shall be provided at each infant station.
- (e) A free-standing handwashing sink shall be provided in the room.
 - (f) The admission/observation area shall contain:
 - 1. An overhead source of radiant heat;
 - 2. A large wall clock with clearly visible second hand;
 - 3. A flat working surface for charting; and
 - 4. A table or flat surface for trays.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.48 Normal newborn nursery (Level I)

- (a) Normal newborn nurseries shall be located close to the postpartum unit and shall be inaccessible to unrelated traffic.
- (b) The number of bassinets shall exceed the number of licensed obstetric beds by at least 20 percent, in order to accommodate multiple births and extended hospitalization beyond mother's discharge date, as well as beyond 28 days.
- (c) A minimum of 24 square feet for each bassinet 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 12 bassinets shall be permitted in one normal newborn nursery.
- (e) One oxygen outlet, one compressed air outlet and one suction outlet for every six infant stations shall be provided. One such group of outlets shall be located at each end of the room.

- (f) Two single or one duplex wall-mounted electrical outlets shall be provided for every two infant stations.
- (g) A free-standing handwashing sink 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.
 - (h) A soiled utility room shall be provided.
 - (i) A clean utility room or area shall be provided.
- (j) A parent room shall also be provided, to be used for breast feeding after mother's discharge and for sibling visitations. The parent room shall be equipped with a handwashing sink.
- (k) 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.
- (1) Storage facilities for the newborn nursery shall be as follows:
 - 1. There shall be bedside cabinet storage of eight cubic feet per infant station;
 - 2. There shall be three cubic feet per infant for secondary storage of items such as linens and formula within the area; and
 - 3. There shall be six square feet per infant for large items of equipment in a clean storage area.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.49 Continuing care/growing area

- (a) The continuing care/growing nursery shall be provided for low birth weight infants who are not sick but require frequent feedings or infants who no longer require intermediate care but still require more nursing hours and closer observation than normal infants. This area shall be close to the intensive and intermediate care nursery or may be a part of the intermediate care nursery.
- (b) There shall be a minimum of 40 square feet for each infant station with four feet between bassinets.
- (c) There shall be one oxygen outlet, one compressed air outlet and one suction outlet for each infant station.
- (d) There shall be four electrical outlets for each infant station.
- (e) If the continuing care nursery is a separate nursery, then a separate work area with a scrub sink shall be provided.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.50 Isolation nursery

- (a) Each isolation nursery shall be an enclosed and separate room within the newborn nursery unit.
- (b) The isolation nursery shall provide a minimum of 40 square feet of space per infant, exclusive of lavatory. There shall be a minimum of two stations with either one room or two rooms which may share a common anteroom.
- (c) A free-standing handwashing sink shall be provided at the entrance inside the isolation nursery anteroom with foot or knee control.
- (d) One oxygen outlet, one compressed air outlet and one suction outlet shall be provided for each infant station.
- (e) Four electrical outlets shall be provided for each infant station.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.51 Intermediate care nursery (Level II)

- (a) The intermediate care nursery shall be located away from general hospital traffic and should be close to the delivery room and the intensive care nursery.
- (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 compressed air outlets and two suction outlets.
- (d) Eight electrical outlets shall be provided for each infant station. A separate outlet shall be provided to supply power for a portable X-ray machine for the intermediate care nursery.
- (e) A free-standing handwashing sink, 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.
 - (f) A soiled utility room shall be provided.
 - (g) A clean utility room or area shall be provided.
- (h) Storage facilities for the intermediate care nursery (Level II) shall be as follows:
 - 1. There shall be eight cubic feet of storage for each infant care station for supplies needed for immediate use of shelves and cabinets within patient area;
 - 2. There shall be at least 20 square feet of floor space for equipment for each infant care station adjacent to or

with the intermediate care nursery outside of the patient area; and

3. There shall be 16 cubic feet of shelf or cabinet space for each infant care station adjacent to or within this area but outside of the infant care area.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.52 Intensive care nursery (Level III)

- (a) The intensive care nursery shall be near the delivery room and shall be accessible from an ambulance entrance. This area 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 compressed air outlets and four suction outlets for each infant care station.
- (d) There shall be 16 electrical outlets for each infant care station. A separate outlet shall be provided to supply power for a portable X-ray machine to serve the neonatal area.
- (e) Storage facilities for the intensive care nursery (Level III) shall be as follows:
 - 1. There shall be 16 cubic feet of storage counter and cabinet for supplies needed for immediate use within the infant's room for each infant care station;
 - 2. There shall be at least 30 square feet of floor space adjacent to or within the intensive care nursery but outside of patient area for each infant care station; and
 - 3. There shall be 24 cubic feet of shelf or cabinet space adjacent to or within the intensive care nursery but outside of the patient area for each infant care station.
 - (f) A soiled utility room shall be provided.
 - (g) A clean utility room or area shall be provided.
- (h) A free-standing handwashing sink shall be provided at the entrance to the intensive care nursery. One sink with foot or knee controls shall be provided for every three infant care stations within the nursery.
- (i) There shall be on-call room(s) for staff on the same floor of the hospital with an adjoining toilet, lavatory and shower.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

8:43G-19.53 Shared services (Level II and Level III)

- (a) If intermediate care nursery (Level II) and intensive care nursery (Level III) are located in the same suite, then the following services may be shared:
 - 1. Janitor's closet;
 - 2. Soiled utility;
 - 3. Clean utility;
 - 4. Demonstration/conference room;
 - 5. Storage room;
 - 6. Formula storage room;
 - 7. Male/female staff lockers, lounge and toilets;
 - 8. Parent waiting room;
 - 9. Consultation room;
 - 10. Public toilet and telephone; and
 - 11. On-call room.

New Rule, R.1990 d.422, effective September 4, 1990. See: 21 N.J.R. 3642(a), 22 N.J.R. 2705(a).

SUBCHAPTER 20. EMPLOYEE HEALTH

8:43G-20.1 Employee health policies and procedures

- (a) Employee health service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies and procedures shall be readily available for employees to review and include at least the following:
 - 1. The content and frequency of employee health examinations by a physician;
 - 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Clinical restrictions added at (a)5. Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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 or physician, 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) Each new employee, including members of the medical staff employed by the hospital, upon employment, shall receive a two-step Mantoux tuberculin skin test with five tuberculin units of purified protein derivative. The only exceptions are employees with documented negative Mantoux skin test results (zero to nine millimeters of induration) within the last year, employees with documented positive Mantoux skin test results (10 or more millimeters of induration), employees who received appropriate medical treatment for tuberculosis, or when medically contraindicated. Results of the Mantoux tuberculin skin tests administered to new employees shall be acted upon as follows:
 - 1. If the first step of the Mantoux tuberculin skin test result is less than 10 millimeters of induration, the test shall be repeated one to three weeks later.
 - 2. If the Mantoux test is 10 millimeters or more of induration, a chest x-ray is performed and, if necessary, followed by chemoprophylaxis or therapy.
- (e) Each employee, including members of the medical staff employed by the hospital, shall receive an annual Mantoux tuberculin skin test. The only exceptions are those employees exempted at (d) above. Results of positive Mantoux tuberculin skin tests administered to employees shall be acted upon in accordance with (d)2 above.
- (f) 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 inoculation with rubella vaccine, or when medically contraindicated.
- (g) Each new employee, including members of the medical staff employed by the hospital shall be given a rubella screening test upon employment in accordance with (e) above.
- (h) 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 by March 1, 1992. 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.

- (i) 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, in accordance with (g) above.
- (j) The hospital shall offer rubella and rubeola vaccination to all employees and medical staff.
- (k) The hospital shall maintain a list identifying the name of each employee who is seronegative and unvaccinated.
- (1) The hospital shall comply with the reporting requirements of the Department of Health's 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 Communicable Disease Control Services CN 369 Trenton, NJ 08625-0369

- (m) The hospital shall provide initial health care for employees who become ill or are injured while at work.
- (n) 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.
- (o) 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text added at (f)-(i) on rubella/rubeola.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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 quality assurance methods

There is a program of quality assurance for employee health that is integrated into the hospital quality assurance program and includes regularly collecting and analyzing data to help identify employee health problems and their extent,

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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 annually, revised as needed, and implemented. They shall include at least:
 - 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 quality assurance methods

There shall be a program for quality assurance for oncology 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.

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 annually, revised 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Safety requirements added at (a)9.

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-22.3

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Guardians added at (e).

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 Pediatrics and pediatric intensive care quality assurance methods

There shall be a program of quality assurance for each pediatric service 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, recommending, implementing, and monitoring corrective actions on the basis of these data.

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Safety requirements deleted (see 22.2).

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;
 - 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Parent overnight stay added at (c).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic changes.

8:43G-22.21 (Reserved)

8:43G-22.22 Pediatric intensive care quality assurance methods

The quality assurance program for pediatric intensive care shall include interhospital exchanges of information and case reviews with pediatric specialists in other hospitals.

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Pharmacist added to (b).

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 of food/drug interactions and responsibility of pharmacy, nursing, and dietary services;
- 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text on self-administration of drugs added at (a)13.

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 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 num-

- ber), 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.
- (1) 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Written communication specified at (f).

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 quality assurance methods

- (a) There shall be a program of quality assurance for the pharmacy service 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 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

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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 assurance 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 annually, revised 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 annually, revised 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 Community Affairs, and the Guidelines for Construction and Equipment of Hospital and Medical Facilities (1987 edition, as published by The American Institute of Architects Press, 1735 New York Ave., NW, Washington, D.C. 20006, Pub. No. ISB N0-913962-96-1). 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 the Construction and Monitoring Program, Health Facilities Evaluation, New Jersey Department of Health, CN 367, Trenton, N.J. 08625-0367, for approval prior to construction, alteration, or renovation.

8:43G-24.9 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of July 1, 1979 through May 7, 1981 or May 8, 1981 through October 1, 1987; mandatory".

8:43G-24.10 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of August 1, 1977 through July 1, 1979; mandatory".

8:43G-24.11 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995.

See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant general compliance for construction, alteration or renovation completed during the period of September, 1974 to August 1, 1977; mandatory".

8:43G-24.12 (Reserved)

Repealed by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

Formerly "Physical plant maintenance general compliance for construction, alteration or renovation completed prior to September, 1974; mandatory".

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
- (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 within 72 hours. In addition, a written report of the investigation shall be forwarded to the Department of Health as soon as it becomes available.
- (1) 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Most recent two inspections to be on file.

8:43G-24.14 (Reserved)

SUBCHAPTER 25. POST MORTEM

8:43G-25.1 Policies and procedures

(a) The morgue shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies shall delineate the responsibil-

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ities of the medical staff, nursing, and morgue 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 house-keeping 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Identification, handling and reporting requirements further specified at (a)6, 7 and 10.

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;
 - 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Discharge criteria deleted; seclusion, restraint and ECT standards added

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Effective date added at (b).

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 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 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;
 - 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:
 - 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.
- (1) 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 be at 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Exercise requirements added at (f).

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.

SUBCHAPTER 27. QUALITY ASSURANCE

8:43G-27.1 Quality assurance structural organization

- (a) The governing authority of the hospital (such as the board of trustees) shall have ultimate responsibility for the quality assurance program.
- (b) The hospital shall have a hospital-wide quality assurance program based on a written quality assurance plan that is implemented and that monitors the quality of patient care.
- (c) Each clinical department shall have quality assurance activities that are part of the overall hospital-wide plan, a multi-department plan, or an internally generated plan.
- (d) There shall be a multidisciplinary committee responsible for the direction of the quality assurance program. The committee shall include at least representation from the medical staff, nursing, and administration. The committee shall establish a mechanism to include participation of all disciplines in identifying areas of review that affect patient care throughout the hospital.
- (e) The hospital shall perform risk management functions. Reports generated by risk management activities shall be routinely provided to the multidisciplinary committee responsible for coordinating the quality assurance program.

8:43G-27.2 Quality assurance policies and procedures

- (a) The quality assurance plan shall be reviewed at least annually and revised as necessary. Responsibility for reviewing and revising the plan shall be designated in the plan itself.
- (b) The quality assurance plan shall delineate lines of communication between the quality assurance program and the medical staff, chief executive officer or administrator, and governing authority.
- (c) The hospital-wide quality assurance plan shall specify procedures for the development, implementation, and coordination of quality reviews. The plan shall also establish a mechanism for the evaluation of the quality assurance program.

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(d) The program shall disseminate its findings and the results of quality assurance activities, as defined in the quality assurance plan.

8:43G-27.3 Quality assurance staff qualifications

There shall be an individual responsible for coordinating all aspects of the quality assurance program.

8:43G-27.4 (Reserved)

8:43G-27.5 Quality assurance 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 quality assurance coordinator shall be available to provide ongoing consultation to each department including assistance with the development of specific indicators used to evaluate service outcomes 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 quality assurance 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 quality assurance program.
- (e) The quality assurance program shall provide information that is utilized in the evaluation of the clinical competence of all clinical practitioners.

8:43G-27.6 (Reserved)

SUBCHAPTER 28. RADIOLOGY

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). CN approval required for off-site service.

8:43G-28.2 Radiology policies and procedures

- (a) The radiology service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. These policies and procedures 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 quality assurance methods

There shall be a program of quality assurance for the radiology service 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.

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (b) on radiologic technician availability.

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Ultrasound required in (d).

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 therapy services staff qualifications

- (a) All physicians performing radiation therapy services in the hospital shall have successfully completed an approved residency training program in radiology or radiation therapy.
- (b) All radiation therapy technologists in the radiation therapy service shall be licensed.

8:43G–28.14 Radiation therapy services staff time and availability

- (a) A radiation oncologist shall be available on-site or oncall; if on-call, he or she shall be able to arrive and shall arrive at the hospital within four hours of being summoned.
- (b) There shall be at least one licensed radiation therapy technologist or radiation oncologist present to operate each cobalt machine when it is in use.
- (c) There shall be at least two radiation therapy technologists present to operate each linear accelerator when it is in use. A radiation oncologist may act as a substitute for one of the two technologists.
- (d) A radiation physicist shall be available to the radiation therapy service on a full- or part-time basis.
- (e) A registered professional nurse shall be available on a full- or part-time basis to the radiation therapy unit.
- (f) A professional member of the social work department shall be available on a full- or part-time basis to the radiation therapy unit to meet the psychosocial needs of radiation therapy patients and families.

8:43G-28.15 (Reserved)

8:43G-28.16 Radiation therapy services patient services

- (a) A written plan or care shall be developed upon initiation of treatment for each radiation therapy patient.
- (b) Individual patient records of radiation therapy 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 therapy treatments shall be included in the patient's medical record, if applicable.

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- (c) Computerized treatment planning for radiation therapy 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 according to a plan developed by a radiation physicist. The review shall be conducted by a physicist, chief technologist, or dosimetrist.
- (e) A periodic review of all cases under treatment shall be conducted and at least one verification film shall be made every three weeks for each patient under treatment.

8:43G-28.17 (Reserved)

8:43G-28.18 Radiation therapy services supplies and equipment

- (a) Each radiation therapy department that has a linear accelerator shall have at least one simulator.
- (b) Emergency drugs shall be immediately available to the radiation therapy service.

Law Review and Journal Commentaries

Health Law-Hospitals. Steven P. Bann, 136 N.J.L.J. 66 (1994).

8:43G-28.19 Radiation therapy services quality assurance methods

There shall be a program of quality assurance for radiation therapy 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, recommending, implementing, and monitoring corrective actions on the basis of these data.

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)

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 annually, revised 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 the rapy 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 assurance methods

(a) There shall be a program of quality assurance for physical therapy 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.

8:43G-29.13 Occupational therapy policies and procedures

- (a) The occupational therapy service shall have written policies and procedures that are reviewed annually, revised 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.

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- (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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Contracting requirements specified at (h).

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 onsite.
- (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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Physician's order added at (b).

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 quality assurance methods

(a) There shall be a program of quality assurance for occupational therapy 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.

SUBCHAPTER 30. RENAL DIALYSIS

8:43G-30.1 Scope of renal dialysis standards

The standards in this subchapter shall apply only to hospitals that have an on-site separate, designated unit or service for renal dialysis. If a hospital has a renal dialysis unit or service, the standards shall apply to both hemodialysis and peritoneal dialysis units, and to both chronic and acute treatment.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). On-site added.

8:43G-30.2 Renal dialysis policies and procedures

- (a) The renal dialysis service shall have written policies and procedures that are reviewed annually, revised as needed, and implemented. They shall include at least:
 - 1. Criteria for acceptance of patients into the chronic dialysis service, including assurance that patients who have communicable or transmittable diseases will be accepted;
 - 2. Handling the abusive or disruptive patient;

- 3. Orientation of new patients to the unit;
- 4. Medical and non-medical emergency procedures involving situations that occur during hours of operation and at other times, including, for example, equipment failure, medical emergency, and codes;
- 5. Instructing patients and medical staff about the medical and non-medical emergency procedures; and
- 6. The circumstances under which patients may bring food into the unit.
- (b) The renal dialysis service shall have written infection control policies and procedures specific to the renal dialysis unit that includes universal precautions and meets at least the criteria of the hospital-wide infection control program.
- (c) All staff members of the renal dialysis service shall be screened for hepatitis in accordance with the current edition of the Centers for Disease Control publication "Hepatitis Surveillance", as amended and supplemented, available from the Centers for Disease Control, Atlanta, Georgia 30333.
- (d) The hospital shall provide an immunization program against hepatitis for all renal staff.
- (e) The renal dialysis service shall maintain a written transfer agreement with an organ transplantation center for referral of patients.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic change.

8:43G-30.3 Renal dialysis staff qualifications

- (a) Renal dialysis services shall be under the supervision of a health care professional with at least one of the following qualifications:
 - 1. A baccalaureate degree in a health care discipline from an accredited college or university and the equivalent of at least two years of full-time experience in renal dialysis; or
 - 2. Five years full-time experience in renal dialysis experience and documentation of progressive supervisory experience for at least one year.
- (b) Any physician currently holding the position of director of a renal dialysis unit shall have completed a residency in nephrology and shall be able to demonstrate skills and experience at least equivalent to certification by the American Board of Internal Medicine, subspecialty in Nephrology. Any newly appointed physician director shall be board certified in Nephrology, or shall meet the training and experience requirements for examination by the Board and shall be examined within two years of eligibility.

- (c) A registered dietitian with at least one year of clinical experience as a registered dietitian shall be assigned to the renal dialysis unit.
- (d) The social worker assigned to the renal dialysis unit shall have at least:
 - 1. A master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or
 - 2. A bachelor's degree from an accredited social work program and one year of experience in social work, if the person was hired prior to 1976.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Bachelor's degree acceptable if hired before 1976.

8:43G-30.4 (Reserved)

8:43G-30.5 Renal dialysis staff time and availability

- (a) There shall be a registered professional nurse with administrative or clinical responsibility for all nursing care in the dialysis service.
- (b) There shall be at least one registered professional nurse (RN) on duty at all times in the unit while care is being provided.
- (c) There shall be at least one RN, licensed practical nurse, or trained technician on duty in the unit for every three patients receiving care.
- (d) Two of the nurses on duty in the unit shall be RNs whenever care is being provided to more than six patients.
- (e) Nurses on the renal dialysis staff shall receive on-site training in renal dialysis techniques as determined by the hospital before they are permitted to work unsupervised with patients.
- (f) The medical director or designated nephrologist shall be on site or on call at all times when the unit is in operation.
- (g) The medical director or designated nephrologist and a registered professional nurse shall be on call when the unit is not in operation.
- (h) A registered dietician shall be assigned either part time or full time to the renal dialysis unit.
- (i) A social worker shall be assigned either part time or full time to the renal dialysis unit.

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Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). R.N. to supervise dialysis unit nursing care.

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8:43G-30.6 Renal dialysis patient services

- (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 registered dietitian, and a social worker and shall include goals and expected outcomes.
- (b) The written plan of care for the chronic renal dialysis patient shall be reviewed with the patient and/or family, implemented within four weeks of admission to the program, reviewed at least every six months, and revised if change has occurred. The written plan of care for the acute dialysis patient shall be implemented within 24 hours of initiation of acute dialysis and revised and updated weekly.
- (c) Notes shall be entered for the chronic dialysis patient by each member of the multidisciplinary team that reflects the patient's response to the plan of care and makes recommendations for changes in the plan of care at least two times a year.
- (d) There shall be multidisciplinary committee meetings that take place on a periodic basis to discuss multidisciplinary communication, management, and issues about the care of patients treated in the dialysis unit. The committee shall include representatives from at least nursing, the medical staff, dietary services, and social work services.
- (e) The renal dialysis service shall adhere to the principles set out in the Trans-Atlantic Renal Council's Bill of Rights for renal patients.
- (f) The hospital's policy on dialyzer reuse shall be explained to all renal dialysis patients. Patients who consent to reuse shall sign an informed consent form. If the patient declines reuse, arrangements shall be made for the patient to receive single-use treatment in the unit.
- (g) If patients are permitted to bring food into the renal dialysis unit, they shall not be permitted to share it and must use only personal utensils, wrappers, and containers.
- (h) All patients shall be screened for hepatitis and in accordance with the current edition of the Centers for Disease Control publication "Hepatitis Surveillance."
- (i) Renal dialysis patients with communicable or transmittable diseases shall be treated in accordance with Centers for Disease Control guidelines.

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
- (j) If a renal dialysis patient is referred by, or is from, another health care facility, the renal dialysis service shall provide that facility with copies of summaries of the patient's progress, including dietary care, and results of laboratory tests upon discharge from the renal program or upon request from the facility.
- (k) If a hospital provides home care training in renal dialysis, the training shall be directed by a registered professional nurse (RN). There shall be at least one RN or licensed practical nurse assigned to every two patients undergoing training on-site.
- (1) The home (self) care training program shall have a written outline of course material for persons undergoing training which shall include didactic and practical sessions to prepare trained patients and/or helpers to perform unsupervised dialysis treatments.
- (m) If a hospital has a home (self) care training program, the hospital shall provide, either directly or through agreement with another health care facility, the following services:
 - 1. Surveillance of the patient's home adaption, including provisions for visits by a staff member to the home and by the patient to the hospital;
 - 2. Documentation in the patient's medical record of the number and content of surveillance visits;
 - 3. Ensurances that patient teaching materials are available for patient use during and after home (self) care dialysis training and at times other than during the dialysis procedure;
 - 4. Consultation for the patient with a social worker and a dietician:
 - 5. A recordkeeping system which ensures continuity of care;
 - 6. Installation and maintenance of equipment in the home;
 - 7. Testing and treatment of the water in the home, according to current industry wide practices for home dialysis; and
 - 8. Ordering of supplies for the home on an on-going basis.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Home care requirements added.

8:43G-30.7 (Reserved)

8:43G-30.8 Renal dialysis supplies and equipment

- (a) Patients shall be dialyzed in chairs that can be inclined so that the patient's head is lower than his or her feet, except when the patient is dialyzed in a hospital bed.
- (b) Any reuse of a dialyzer shall conform with guidelines in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Recommended Practice for Reuse of Hemodialyzers," incorporated herein by reference.
- (c) Water treatment equipment, water and dialysate shall conform with the requirements in the AAMI publication "American National Standard for Hemodialysis Systems", as amended and supplemented, incorporated herein by reference. Water and dialysate shall be microbiologically analyzed monthly. Water samples shall be taken immediately following the last water treatment device and at locations in the treatment area which will assure the water throughout the distribution lines conforms with AAMI standards. Chemical analysis of the water shall be performed every six months.
- (d) A DPD test kit or similar method shall be used daily to detect chloramine break through and chloramine levels in water used to prepare dialysate and shall not exceed the AAMI standard of 0.1 ppm.

Note: AAMI publications can be obtained from:

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

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text at (c) and (d) deleted; new text added.

8:43G-30.9 Renal dialysis staff education and training

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

8:43G-30.10 (Reserved)

8:43G-30.11 Renal dialysis quality assurance methods

There shall be a program of quality assurance for the renal dialysis service 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. The program monitors those indicators required by the Trans–Atlantic Renal Council and shall include monitoring of home dialysis patients.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Home dialysis included.

8:43G-30.12 (Reserved)

8:43G-30.13 Physical plant general compliance for new construction, alteration, or renovation

- (a) Physical plant standards for acute renal dialysis services shall be in compliance with N.J.A.C. 5:23–3.2 of the New Jersey Uniform Construction Code.
- (b) The hospital shall submit plans and specifications to the Construction and Monitoring Program, Health Facilities Evaluation, New Jersey Department of Health, CN 367, Trenton, N.J. 08625–0367, for review and approval prior to construction, alteration, or renovation.
- (c) Prior to approval, plan review fees shall be submitted, in accordance with N.J.A.C. 8:31–1.1.

New Rule, R.1990 d.423, effective September 4, 1990. See: 21 N.J.R. 3406(a), 22 N.J.R. 2708(a).

8:43G-30.14 Treatment area requirements for acute renal dialysis services

- (a) The treatment area for acute renal dialysis services shall be an open planned area separated from administrative and service areas.
- (b) The floor area allocated for each machine shall be 100 square feet, with a net usable area of 80 square feet, with 30 inches of clear space maintained around each machine or lounge. Machines may be installed flush against the wall on one side only. There shall be a four foot space between beds or lounges.
- (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 and shall provide visibility of all patients' stations.
- (e) Charting facilities for nurses and doctors shall be located adjacent to the nurses' station.
- (f) Handwashing facilities shall be provided at a ratio of one handsink per every three stations and shall be distributed throughout the dialysis area.

New Rule, R.1990 d.423, effective September 4, 1990. See: 21 N.J.R. 3406(a), 22 N.J.R. 2708(a).

8:43G-30.15 Service areas requirements for acute renal dialysis service

(a) The size and location of each service area for acute renal dialysis services shall be based upon the number of beds or lounges to be served. The following service areas

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shall be located within the dialysis suite and readily available to the open treatment area:

- 1. Preparation space, which shall be adjacent to the open treatment area;
- 2. Separate clean and soiled work or utility rooms, which shall be within the suite. Soiled and clean utility rooms shall contain a minimum of 80 square feet each. Clean linen and clean utility room may be combined, and if combined, shall contain a minimum of 120 square feet and shall contain handwashing facilities. Soiled holding and soiled utility room may be combined, and if combined, shall contain a minimum of 120 square feet and shall contain handwashing facilities;
- 3. A separate janitor's closet, which shall be provided exclusively for the renal suite. The closet shall contain a floor receptor or service sink and storage space for house-keeping 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. Employees shall not be permitted to eat in the dialysis treatment area;
- 5. Office space, which shall be provided for the medical director and nurse supervisor;
- 6. A lounge, locker room and staff toilet with hand-washing facilities, which shall be available for staff;
- 7. A separate toilet room with handwashing facilities, which shall be provided for patients;
- 8. A drug distribution station, which may be a medicine preparation room or unit, a self-contained medicine dispensary unit, or another approved system. If used, a medicine preparation room or unit shall be under the nursing staff's visual control and contain a work counter with handwashing facilities, refrigerator, and locked storage for biologicals and drugs. A medicine dispensary unit may be located at the nurses' station, in the clean workroom, or in an alcove or other space under direct control of the nursing or pharmacy staff;
- 9. A nourishment station, which shall contain a sink equipped for handwashing, equipment for serving nourishment, refrigerator, storage cabinets and ice maker-dispenser unit;
- 10. Equipment and emergency storage room(s), which may be a combined unit. The size shall be determined by the needs in the program and the equipment to be stored;
- 11. A storage room or rooms, which shall be located either within or outside of the suite, which shall house the working equipment to maintain the equipment applicable to the machines for the dialysis suite. At least one week of operation supplies must be available in the facility. There shall be 70 square feet per machine/station of storage;

- 12. Storage space, which shall be provided for wheel-chairs and stretchers out of direct line of traffic;
- 13. Storage space for renal waste, which shall be provided within the unit until it is properly disposed;
- 14. Patient toilet rooms, which shall have doors equipped with hardware which will permit access by staff in any emergency; and
- 15. Home training rooms or areas, which, if provided, shall be equipped with a sink for handwashing.

New Rule, R.1990 d.423, effective September 4, 1990. See: 21 N.J.R. 3406(a), 22 N.J.R. 2708(a).

8:43G-30.16 Emergency generator and water supply

- (a) An emergency generator shall be provided in a room which shall have a one-hour fire rating with an approved fresh air intake and an explosion release. All machines shall be connected to the emergency generator so that all machines will operate for at least four hours following a power shutdown or outage.
- (b) Water supply systems shall be designed to supply water to the fixtures and equipment on the upper floors at a minimum pressure of 15 pounds per square inch during periods when fixtures and equipment are in use.

New Rule, R.1990 d.423, effective September 4, 1990. See: 21 N.J.R. 3406(a), 22 N.J.R. 2708(a).

8:43G-30.17 Functional requirements for pediatric dialysis services

- (a) If separate pediatric dialysis services are provided, the services for young children and adolescents shall be housed in a unit separate from the services provided to adults.
- (b) The area housing the pediatric dialysis unit shall be located within the treatment area.
- (c) The area allocated per patient dialysis station shall be the same net usable square foot area as required in N.J.A.C. 8:43G–30.13.
- (d) The area housing the pediatric dialysis unit shall be enclosed with fixed partitions that extend from finished floor to ceiling. Vision panels in partitions are required.
- (e) The pediatric dialysis unit shall have handwashing facilities separate from the adult unit.
- (f) Pediatric dialysis service areas may be shared with the adult unit.

New Rule, R.1990 d.423, effective September 4, 1990. See: 21 N.J.R. 3406(a), 22 N.J.R. 2708(a).

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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

8:43G-31.2 Respiratory care policies and procedures

- (a) The respiratory care service shall have written policies and procedures that are reviewed annually, revised 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Administrative Correction.

See: 22 N.J.R. 653(a).

Amended by R.1995 d.124, effective March 20, 1995.

See: 27 N.J.R. 1290(a).

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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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 CO₂ monitors shall be available for patients in the hospital who have a medical

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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 Quality assurance methods

There shall be a program of quality assurance for respiratory care 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.

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 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 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Text added at (a)6; minor local blocks excluded at (a)9.

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 services 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 physician within 14 days 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Documentation requirements added.

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 service quality assurance methods

(a) There shall be a program of quality assurance for same-day surgery 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. Quality assurance 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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Text added at (b).

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.

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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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic changes.

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 quality assurance methods

- (a) There shall be a program of quality assurance for the same-day medical service 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 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.

SUBCHAPTER 33. SOCIAL WORK

8:43G-33.1 Social work structural organization

Each hospital shall have an organized department of social work services that is directed by a social worker.

8:43G-33.2 Social work policies and procedures

- (a) The social work department shall have written policies and procedures that are reviewed annually, revised 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 work department shall have criteria for identifying 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.

Amended by R.1995 d.124, effective March 20, 1995. See: 26 N.J.R. 4537(a), 27 N.J.R. 1290(a).

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.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Guardians added.

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 quality assurance methods

There shall be a program of quality assurance for social work that is integrated into the hospital quality assurance program and pertains to the scope of social work services provided. This 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 annually, revised as needed, and implemented. They shall include at least:
 - 1. Aseptic practices;
 - 2. Infection control policies for the surgical suite, including attire;
 - 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, which includes bagging and covering soiled laundry at the site of use before transport to the soiled holding area and removing soiled laundry from each operating room following every procedure.



8:43G-34.4 Surgery staff qualifications

- (a) There shall be a physician director who has clinical responsibility for the surgical service who is board certified. Certification shall be by a board of the American Board of Medical Specialists.
- (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 have training 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) There shall be a system to verify patient identification prior to any surgical procedure.
- (b) There shall be a system to ensure that surgical patients' personal effects are secured during surgery.
- (c) 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.
- (d) 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 signed by the patient or legal guardian that includes identification of the physician(s) performing the procedure prior to all procedures requiring informed consent;
 - 2. A completed preoperative checklist; and
 - 3. A medical history and the results of a physical examination.

- (e) The surgical suite nursing staff shall make a perioperative 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 nursing care and patient reactions while in the operating suite.
- (f) Operative reports shall be dictated or written in the medical record immediately after surgery.
- (g) 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.
- (h) There shall be a system in place for obtaining frozen section results on a timely basis.
- (i) There shall be documentation of perioperative patient education.

8:43G-34.7 Surgery space and environment

- (a) The surgical 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) All staff in the surgical suite shall be attired in scrub attire. Individuals permitted limited access may wear cover gowns or jumpsuits as substitutes.
- (c) Trash shall be collected in closed containers in each operating room before transport to the soiled holding area. All trash shall be removed from each operating room after each patient is discharged from the operating room.

8:43G-34.8 Surgery supplies and equipment

- (a) The emergency equipment in the surgical suite shall include at least an emergency communication system that connects each operating room and postanesthesia care unit with the control center of the suite, a cardiac monitor, a resuscitator, an ambu bag, a defibrillator, a suction set, a thoracotomy set, a tracheostomy set and endotracheal tubes. This equipment shall be available in sizes adaptable to newborns, infants, and children. 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 daily 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) Staff who have been handling soiled linens or supplies shall wash their hands properly before handling clean linen and supplies.
- (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 quality assurance methods

- (a) There shall be a complete and current record of all surgical procedures.
- (b) There shall be a program of quality assurance for the surgical suite 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.

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 annually, revised as needed, and implemented. They shall include at least:
 - 1. Criteria for admission to and discharge from the unit;
 - 2. Delineation of the primary medical responsibility for postanesthesia and postsurgical care of 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; mandatory

4.4

(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) All registered professional nurses assigned to the postanesthesia care unit shall be trained in postanesthesia care, including at least:
 - 1. The 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. Cardiopulmonary resuscitation;
 - 7. Administration of drugs and identification of drugrelated problems; and
 - 8. Recognition of the actions and interactions of anesthetic techniques.
- (d) All registered professional nurses in the postanesthesia care unit shall have training in basic cardiac life support.
- (e) All registered professional nurses in the postanesthesia care unit shall have training in critical care.

Amended by R.1992 d.72, effective February 18, 1992. See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a). Stylistic changes.

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.

Administrative Correction to (a): Added text. See: 22 N.J.R. 1265(b).

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

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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 blood pressure, pulse, and respiration, are recorded.
- (d) The postanesthesia care unit 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.
- (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 medical 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, 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 specified 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 restricted zone of the postanesthesia care unit shall be through or past a control center.
- (c) All staff in the postanesthesia care unit shall be attired in scrub attire. Individuals who are permitted limited access may wear cover gowns or jumpsuits as substitutes.
- (d) Equipment available in the postanesthesia care unit shall include at least: emergency equipment and drugs, pulse oximetry, equipment necessary for extubation, respirometer, various means of oxygen delivery, constant and intermittent suction, blood pressure monitoring, adjustable lighting, immediate access to ventilator, and equipment which ensures protection of the patient's privacy.

8:43G-35.7 Postanesthesia care staff education and training

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

8:43G-35.8 (Reserved)

8:43G-35.9 Postanesthesia care quality assurance methods

- (a) There shall be a program of quality assurance for the postanesthesia care unit that is integrated into the hospital 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.
- (b) Quality assurance activities shall include at least monitoring outcomes of patients receiving anesthetic agents.