Rhode Island Department of Health

PUBLIC NOTICE

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

The following seventy-five (75) regulations are proposed to be amended:

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
68. Rules and Regulations Pertaining to the Medical Examiner System
69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
73. Rules and Regulations Related to the Medical Marijuana Program
74. Rules and Regulations Related to the Practice of Electrolysis
75. Rules and Regulations Relating to Emergency Medical Services

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Notice is hereby given in accordance with the provisions of §42-35-3(a)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened*. Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received*. All regulations for which a public hearing is not requested will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the 10 September 2012 deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 2012**. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

Copies of all regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, on the Secretary of State's website: http://www.sos.ri.gov/rules/, by calling 401-222-7767, or by e-mail to Bill.Dundulis@health.ri.gov.

Signed this 3rd day of August 2012

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

RULES AND REGULATIONS
FOR LICENSING OF HOSPITALS

[R23-17-HOSP]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH
August 1973

***AS AMENDED*:**

February 1974
July 1974
May 1977
April 1979
March 1980
December 1980
August 1982
February 1984 (E)
May 1984 (E)
June 1985
August 1985
January 1987 (E)
May 1987
September 1987
October 1988
August 1989
December 1990
January 1991(E)
October 1991
July 1995 (E)
November 1995(E)
September 1996 (E)
October 1996
October 1996 (T)
January 1997 (E)
April 1997
July 1997 (E)
July 1997 (E)
October 1997
May 1998
June 1998 (T)
September 1998 (E)
January 1999 (E)
April 1999
May 1999 (E)
September 1999 (E)
November 1999
January 2000
May 2000
July 2000 (E)
November 2000 (E)
November 2001
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
March 2002
July 2002
December 2002
August 2004
March 2005
January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
September 2007
April 2009
January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
August 2012 (Proposed)

COMPILER'S NOTES:
Proposed Additions: Underlined
Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended *Rules and Regulations for Licensing of Hospitals (R23-17-HOSP)* are promulgated pursuant to the authority conferred under sections 23-17-10 and 23-17.14-31 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting prevailing standards for licensed hospitals in this state.

The Director of the Department of Health is authorized to establish as part of these regulations quality and volume-related standards to be achieved and maintained for specific tertiary health care services offered by individual licensed health care facilities where peer reviewed medical and health literature establishes significant relationships between desired quality related outcomes and volume of services provided. (See Rhode Island General Laws §23-17-45). Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the regulations: (1) alternative approaches to the regulations; and (2) duplication or overlap with other state regulations.

Based on the available information, no known alternative approach, duplication or overlap was identified.

These amended regulations supersede all previous *Rules and Regulations for the Licensing of Hospitals* promulgated by the Department of Health and filed with the Secretary of State.

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PART I *LICENSING PROCEDURES AND DEFINITIONS*

Section 1.0 *Definitions*

Wherever used in these rules and regulations, the following terms shall be construed as follows:

1.1 ***"Advanced practice clinician",*** as used herein, means an advanced practice nurse licensed in accordance with Chapter 5-34 of the Rhode Island General Laws, as amended; and/or a certified registered nurse anesthetist licensed in accordance with Chapter 5-34.2 of the Rhode Island General Laws, as amended; and/or a midwife licensed in accordance with Section 23-13-9 of the Rhode Island General Laws, as amended; and/or a physician assistant licensed in accordance with Chapter 5-54 of the Rhode Island General Laws, as amended.

1.2 ***"The bed complement"*** of a hospital refers to the number of beds a hospital has in actual use, equal to or less than the licensed capacity.

1.3 "***Bilingual"*** means having fluency in English and in another language.

1.4 ***"Birth center service"*** means a distinct and identifiable unit in a hospital with an obstetrical service, staffed, equipped and operated to provide services to low risk mothers-to-be (as defined in section 40.2.1 herein), or mothers during pregnancy, labor, birth and puerperium.

1.5 ***"Change in operator***" means a transfer by the governing body or operator of a hospital to any other person (excluding delegations of authority to the medical or administrative staff of the facility) of the governing body's authority to:

a) hire or fire the chief executive officer of the hospital;

b) maintain and control the books and records of the hospital;

c) dispose of assets and incur liabilities on behalf of the hospital; or

d) adopt and enforce policies regarding operation of the hospital.

This definition is not applicable to circumstances wherein the governing body of a hospital retains the immediate authority and jurisdiction over the activities enumerated in subsections (a) through (d) herein.

1.6 ***"Change in owner"*** means:

a) in the case of a hospital which is a partnership, the removal, addition or substitution of a partner which results in a new partner acquiring a controlling interest in such partnership;

b) in the case of a hospital which is an unincorporated solo proprietorship, the transfer of the title and property to another person;

c) in the case of a hospital which is a corporation:

(i) a sale, lease, exchange or other disposition of all, or substantially all, of the property and assets of the corporation; or

(ii) a merger of the corporation into another corporation; or

(iii) the consolidation of two or more corporations, resulting in the creation of a new corporation; or

(iv) in the case of a hospital which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or

(v) in the case of a hospital which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.

1.7 ***"Charity care***" means health care services provided by a hospital without charge to a patient and for which the hospital does not and has not expected payment. Said health care services shall be rendered to patients determined to be uninsured, underinsured or otherwise deemed to be eligible at the time of delivery of services. Charity care services are those health care services that are not recognized as either a receivable or as revenue in the hospital's financial statements. Charity care shall not include health care services provided to individuals for the purpose of professional courtesy without charge or for reduced charge. Under no circumstances shall bad debt be deemed to be charity care. Charity care shall be cost-adjusted by applying a ratio of cost to charges from the hospital's Medicare Cost Reports to charity care charges-foregone.

1.8 *"**Clinician**"* means a physician licensed under title 5, chapter 37; a nurse licensed under title 5, chapter 34; a psychologist licensed under title 5, chapter 44, a social worker licensed under title 5, chapter 39.1; a physical therapist licensed under title 5, chapter 40; and a speech language pathologist or audiologist licensed under title 5, chapter 48.

1.9 ***"Conscious sedation"*** means a drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is *not* considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

1.10 ***"Conversion"*** means any transfer by a person or persons of an ownership or membership interest or authority in a hospital, or the assets thereof, whether by purchase, merger, consolidation, lease, gift, joint venture, sale, or other disposition which results in a change of ownership or control or possession of twenty percent (20%) or greater of the members or voting rights or interests of the hospital or of the assets of the hospital or pursuant to which, by virtue of such transfer, a person, together with all persons affiliated with such person, holds or owns, in the aggregate, twenty percent (20%) or greater of the membership or voting rights or interests of the hospital or of the assets of the hospital, or the removal, addition or substitution of a partner which results in a new partner gaining or acquiring a controlling interest in the hospital, or any change in membership which results in a new person gaining or acquiring a controlling vote in the hospital.

1.11 ***"Coronary artery bypass graft",*** as used herein, pertains to surgical operations for the purpose of constructing new pathways around stenosing or obstructing lesions in segments of coronary arteries for the purpose of bringing blood to the myocardium that is otherwise

made ischemic by these lesions. These grafted conduits shall include autologous blood vessels, allograft vessels, and synthetic tubes.

1.12 ***"Degradation (of performance)"*** means an undesired departure in the operational performance of any equipment and/or system from its intended performance. "Degradation" can apply to temporary or permanent failure.

1.13 ***"Director***" shall mean the Director of the Rhode Island Department of Health.

1.14 "***Door-to-balloon time***", as used herein, means the time that elapses from the point in time at which the patient arrives at the PCI hospital to the point in time at which there is balloon inflation in patients who receive primary angioplasty or primary coronary intervention. Reported statistics shall follow applicable guidelines issued by the American College of Cardiology and the American Heart Association.

1.15 ***"Elective percutaneous coronary intervention"***, as used herein, means all percutaneous coronary intervention procedures except primary percutaneous coronary intervention.

1.16 ***"Electromagnetic compatibility (EMC)"*** means the ability of an equipment and/or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance (EMD) to anything in that environment.

1.17 ***"Electromagnetic disturbance (EMD)"*** means any electromagnetic phenomenon that may degrade the performance of an equipment and/or system. An EMD may be an electromagnetic noise, an unwanted signal, or a change in the propagation medium itself.

1.18 ***"Electromagnetic interference (EMI)"*** means degradation of the performance of a piece of equipment, transmission channel, or system caused by an EMD.

1.19 "***Esophageal cancer surgery***", as used herein, means esophageal surgical procedures, performed for the purpose of treating known or suspected cancer, including esophageal resection, partial or total esophagectomy, esophageal anastomosis, and other related procedures excluding endoscopic procedures.[1]

1.20 ***"Equity"*** means non-debt funds contributed towards the capital costs related to a change in owner or change in operator of a hospital which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.

1.21 ***"Fluency***" means the ability to converse freely in a language.

1.22 ***"Health care provider"*** means any person licensed by this state to provide or otherwise lawfully providing health care services, including, but not limited to, a physician, hospital,

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[1] **Compiler's Note:** Review of comments received in conjunction with the 26 February 2009 public hearing on proposed amendments to this definition indicated that additional clarification was needed with regard to the Department's intent. The April 2009 amendments filed with the Secretary of State include technical corrections which provide clarity, but do not change the intent of the definition originally presented at the public hearing.

intermediate care facility or other health care facility, dentist, nurse, optometrist, podiatrist, physical therapist, psychiatric social worker, pharmacist, or psychologist, and any officer, employee or agent of that provider acting in the course and scope of his or her employment or agency related to or supportive of health services.

1.23 ***"Health Services Council"*** shall mean the advisory body to the Rhode Island Department of Health established in accordance with section 23-17-13 of the General Laws, appointed and empowered in accordance with section 23-15-7 of the General Laws to serve as the advisory body to the state agency in its review functions.

1.24 "***Heart transplant"***, as used here, shall include the grafting of a replacement heart into a person with a heart obtained from another person. These standards do not apply to xenografts, nor to artificial or mechanical replacement organs.

1.25 ***"High managerial agent"*** means an officer of the hospital, the chief executive officer, director of risk management, director of nursing services, or any other agent designated by the hospital in a position of comparable authority with respect to the formulation of hospital policies or the supervision of subordinate employees.

1.26 ***"Home care services"*** shall mean a program which is currently administered, and through coordinated planning, evaluation, and follow-up procedures, provides for physician-directed medical, nursing, social, and related services made available either directly or through participating agencies to selected patients having a nexus with a hospital at their place of residence.

1.27 ***"Hospital***" shall mean a facility with a governing body, an organized medical staff and a nursing service providing equipment and services primarily for inpatient care to persons who require definitive diagnosis and treatment for injury, illness or other disabilities or pregnancy. A hospital shall provide psychiatric and/or medical and/or surgical care and at least the following services: dietetic, infection control, medical records, laboratory, pharmaceutical and radiology, except that a psychiatric facility need not provide radiology services.

1.28 ***"Laboratory station"*** means a facility for the collection, processing and transmission of specimens derived from the human body.

1.29 ***"The licensed capacity"*** of a hospital refers to the number of beds a hospital is licensed to operate.

1.30 ***"Licensing agency"*** shall mean the Rhode Island Department of Health.

1.31 ***"Lift team"*** means hospital employees specially trained to perform patient lifts, transfers, and repositioning in accordance with safe patient handling policy.

1.32 ***"Liver transplant"***, as used here, shall include the grafting of a replacement liver into a person with a liver obtained from another person. These standards do not apply to xenografts, nor to artificial or mechanical replacement organs.

1.33 ***"Local anesthesia"*** means the injection of a local anesthetic agent (e.g., Lidocaine) into and around the operative site to achieve numbness in the area where a painful procedure is to be performed. This type of anesthesia does not involve any systemic sedation.

1.34 ***"Musculoskeletal disorders"*** means conditions that involve the nerves, tendons, muscles, and supporting structures of the body.

1.35 ***"Neonatal intensive care unit (NICU)"*** means a unit that provides a comprehensive range of specialty and subspecialty services to severely ill infants, including infants who have an elevated risk of mortality as a consequence of very low birth weight (less than or equal to 1500 grams), surgical conditions, or other forms of severe illness in full-term newborns.

1.36 ***"Net operating revenue"*** means net patient revenue plus other operating revenue.

1.37 "***Non-English speaker***" means a person who cannot speak or understand, or has difficulty in speaking or understanding, the English language, because he/she uses only or primarily a spoken language other than English, and/or a person who uses a sign language and requires the use of a sign language interpreter to facilitate communication.

1.38 ***"Pancreatic cancer surgery"***, as used herein, means pancreatic surgical procedures, performed for the purpose of treating known or suspected cancer, including resection of the pancreas, partial or total pancreatectomy, radical pancreaticoduodenectomy, and other related procedures excluding endoscopic procedures.[2]

1.39 ***Percutaneous coronary intervention (PCI)"***, as used herein, shall include not only conventional balloon angioplasty but also non-balloon procedures including, but not limited to, directional antherectomy, excimer laser, transluminal extraction catheter, rotablation, and coronary stenting and thrombus aspiration.

1.40 ***"Person"*** shall mean any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability companies, state, or political subdivision or instrumentality of a state.

1.41 ***"Physician"*** means any person licensed to practice allopathic or osteopathic medicine pursuant to the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended.

1.42 ***"Premises***" means a tract of land and the buildings thereon where direct patient care services are provided.

1.43 ***"Primary percutaneous coronary intervention"***, as used herein, means percutaneous coronary intervention used as the primary reperfusion strategy, with or without thrombolysis, for known or suspected acute myocardial infarction.

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[2] **Compiler's Note:** Review of comments received in conjunction with the 26 February 2009 public hearing on proposed amendments to this definition indicated that additional clarification was needed with regard to the Department's intent. The April 2009 amendments filed with the Secretary of State include technical corrections which provide clarity, but do not change the intent of the definition originally presented at the public hearing.

1.44 ***Qualified interpreter***" means a person who, through experience and/or training, is able to translate/interpret a particular foreign language into English with the exception of sign language interpreters who must be licensed in accordance with Title 5, Chapter 71.

1.45 *"**Qualified sign language interpreter**"* means one who has been licensed in accordance with the provisions of Title 5, Chapter 71 of the General Laws.

1.46 ***"Radio frequency"*** means a frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion. The present practical limits of radio frequency are roughly 9 kHz to 3000 GHz.

1.47 ***"Regional anesthesia"*** means the use of local anesthetic agents to block nerves leading to the area where a painful procedure is to be done. There are many examples of regional anesthesia, including, but not limited to, spinal, interscalene, ankle, etc. Generally, regional anesthesia involves more of a physiological reaction because of the larger area blocked and/or the dose of local anesthesia. This type of anesthesia may or may not involve sedation.

1.48 ***"Renovation"*** means moving a wall or otherwise changing a structure such that life safety codes or other structural requirements are affected. Normal maintenance of an existing structure is excluded from this definition.

1.49 ***"Reportable event"*** means:

a) fire or internal disaster in the facility which disrupts the provision of patient care services or causes harm to patients or personnel;

b) poisoning involving patient(s) of the facility;

c) infection outbreak as may be defined by and in accordance with reference 21;

d) kidnapping;

e) elopements from inpatient psychiatric units and elopements by minors who are inpatients, (reportable to the Department of Health at the time the local municipal police are informed); elopements of psychiatric patients from outpatient or emergency departments who are reasonably thought to be a danger to themselves or to others;

f) strikes, official strike notices, or other personnel actions that may disrupt services;

g) disasters or other emergency situations external to the hospital environment which adversely affect facility operations; and

h) unscheduled termination of any health care service or utilities vital to the continued safe operation of the facility or to the health and safety of its patients and personnel (including any unanticipated interruption in power to a facility, as well as any event that triggers the use of a backup generator).

1.50 ***"Reportable incidents"*** are those which result in patient injury as defined in a) though j) or which involve matters described in k) through o):

a) brain injury;

b) mental impairment;

c) paraplegia;

d) quadriplegia;

e) any paralysis;

f) loss of use of limb or organ;

g) any serious or unforeseen complication, that is not expected or probable, resulting in an extended hospital stay or death of the patient;

h) birth injury;

i) impairment of sight or hearing;

j) surgery on the wrong patient;

k) subjecting a patient to a procedure/treatment not ordered or intended by the patient's attending physician, excluding procedures not requiring a physician's order, medication errors, and collection of specimen, for laboratory study, obtained by non-invasive means or routine phlebotomy;

l) suicide of a patient during treatment or within five (5) days of discharge from inpatient or outpatient units (if known);

m) blood transfusion error;

n) medication error that necessitates a clinical intervention other than monitoring; or

o) any other incident reported to the malpractice insurance carrier or self insurance program.

1.51 "***Root cause analysis***" means a process for identifying the causal factor(s) that underlie variation in performance.

1.52 ***"Safe patient handling"*** means the use of engineering controls, transfer aids, or assistive devices whenever feasible and appropriate instead of manual lifting to perform the acts of lifting, transferring, and/or repositioning health care patients and residents.

1.53 ***"Safe patient handling policy"*** means protocols established to implement safe patient handling.

1.54 ***"State agency"*** shall mean the Rhode Island Department of Health.

1.55 ***"Tertiary care"*** means services provided by highly specialized providers (e.g.,neonatologists, neurosurgeons, thoracic surgeons). Such services frequently require highly sophisticated equipment and support facilities. As used herein, this care is defined as including, but is not limited to, those services provided in a neonatal intensive care unit.

Section 2.0 ***General Requirements for Licensure***

2.1 No person acting severally or jointly with any other person, shall establish, conduct or maintain a hospital in this state without a license in accordance with the requirements of section 23-17-4 of reference 22.

2.2 A certificate of need is required as a precondition to the establishment of a new hospital, and such other activities in accordance with reference 34.

2.3 Each premises and the related operations of a licensed hospital shall be approved by the Department of Health prior to the inclusion of that premises on the hospital license and commencement of operations at that location.

2.3.1 The hospital shall have a written lease, contract, or other legal document in place for use of space on premises not owned by the hospital.

2.4 The hospital shall maintain current accreditation by any organization granted deeming authority by the federal Centers for Medicare and Medicaid Services (CMS).

2.5 The hospital shall be subject to the provisions of Chapter 23-17.17 of the Rhode Island General Laws, as amended, and the *Rules and Regulations Related to the Health Care Quality Program (R23-17.17-QUAL)* promulgated by the Department. Nothing in the rules and regulations herein should be construed to be inconsistent with the *Rules and Regulations Related to the Health Care Quality Program (R23-17.17-QUAL).*

Section 3.0 ***Application for License or Changes in the Owner, Operator, or Lessee***

3.1 Application for a license to conduct, maintain or operate a hospital shall be made to the licensing agency upon forms provided by it one month prior to expiration date of license and shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to comply with the provisions of reference 22 and of the rules and regulations herein.

3.1.1 Each application shall be accompanied by a non-refundable, non-returnable application fee ~~of sixteen thousand nine hundred dollars ($16,900.00) per facility plus an additional fee of one hundred twenty dollars ($120.00) per licensed bed, made payable to the Rhode Island General Treasurer.~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.*

3.2 Application for changes in the owner, operator, or lessee of a hospital shall be made on forms provided by the licensing agency and shall contain but not be limited to: information pertinent to the statutory purpose expressed in section 23-17-3 of Chapter 23-17 or to the considerations enumerated in section 4.5 herein. An application for a proposed conversion pursuant to the provisions of Chapter 23-17.14 shall contain all information required pursuant to Chapter 23-17.14 as may be determined by the state agency. Further, when review of a proposed change in owner, operator or lessee of a hospital and review of a proposed conversion are both required pursuant to the provisions of Chapter 23-17 and Chapter 23-17.14, respectively, a conversion application shall be filed with the Department

of Health which contains all information required pursuant to Chapter 23-17.14 as may be determined by the state agency; and a separate application for a change in effective control shall be filed containing all information required under the provisions of Chapter 23-17 and section 3.0 herein. Twenty-five (25) copies of the change in effective control application are required to be provided.

3.2.1 Each application filed pursuant the provisions of this section shall be accompanied by a non-refundable, non-returnable application fee, ~~made payable to the Rhode Island General Treasurer, as follows: applicants shall submit a fee equal to two tenths of one percent (0.2%) of the projected annual facility net operating revenue contained in the application; provided, however, that the minimum fee shall be fifteen hundred dollars ($1,500) and the maximum fee shall not exceed twenty thousand dollars ($20,000).~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.*

Section 4.0 ***Issuance & Renewal of License***

4.1 Upon receipt of an application for a license, the licensing agency shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of reference 22 and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection and approval by the licensing agency.

4.1.1 All renewal applications shall be accompanied by a non-refundable, non-returnable annual inspection fee ~~of sixteen thousand nine hundred dollars ($16,900.00) per facility plus an additional fee of one hundred twenty dollars ($120.00) per licensed bed, made payable to the Rhode Island General Treasurer.~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.*

4.2 A license shall be issued to a specific licensee for a specific location(s) and shall not be transferable. The license shall be issued only for the premises and the individual owner, operator or lessee, or to the corporate entity responsible for its governance, as identified in the application.

4.2.1 Any change in owner, operator, or lessee of a licensed hospital shall require prior advisory review by the Health Services Council and approval of the licensing agency as provided in sections 4.4 and 4.5 as a condition precedent to the transfer, assignment or issuance of a new license.

4.2.2 Any conversion of a licensed hospital shall require prior approval of the licensing agency as provided in the *Rules and Regulations Pertaining to Hospital Conversions (R23-17.14-HCA).*

4.2.3 Any change or addition in premises shall require prior review and approval by the Department of Health and amendment of the hospital license.

4.3 A license issued hereunder shall be the property of the state and loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

4.4 Reviews of applications for changes in the owner, operator, or lessee of licensed hospitals shall be conducted according to the following procedures:

a) Within ten (10) working days of receipt, in acceptable form, of an application for a license in connection with a change in the owner, operator or lessee of an existing hospital, the licensing agency will notify and afford the public thirty (30) days to comment on such application.

b) The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.

c) The Health Services Council shall transmit its advisory to the state agency in writing. The decision of the licensing agency shall be based upon the findings and recommendations of the Health Services Council unless the licensing agency shall afford written justification for variance therefrom.

d) All applications reviewed by the licensing agency and all written materials pertinent to licensing agency review, including minutes of all Health Services Council meetings, shall be accessible to the public upon request.

4.5 Except as otherwise provided herein, a review by the Health Services Council of an application for a license, in the case of a proposed change in the owner, operator, or lessee of a licensed hospital, shall specifically consider and it shall be the applicant's burden of proof to demonstrate:

4.5.1 the character, commitment, competence and standing in the community of the proposed owners, operators or directors of the hospital as evidenced by:

(A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, whether within or outside Rhode Island, the demonstrated commitment and record of that (those) person(s):

(i) in providing safe and adequate treatment to the individuals receiving the health care facility's services;

(ii) in encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and

(iii) in providing appropriate access to health care facility services;

(B) A complete disclosure of all individuals and entities comprising the applicant; and

(C) The applicant's proposed and demonstrated financial commitment to the health care facility.

4.5.2 the extent to which the facility will continue, without material effect on its viability at the time of change of owner, operator, or lessee, to provide safe and adequate treatment for individual's receiving the facility's services as evidenced by:

(A) The immediate and long term financial feasibility of the proposed financing plan;

(i) The proposed amount and sources of owner's equity to be provided by the applicant;

(ii) The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the health care facility;

(iii) The relative availability of funds for capital and operating needs;

(iv) The applicant's demonstrated financial capability;

(v) Such other financial indicators as may be requested by the state agency;

4.5.3 the extent to which the facility will continue to provide safe and adequate treatment for individuals receiving the facility's services and the extent to which the facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:

(A) The applicant's demonstrated record in providing safe and adequate treatment to individuals receiving services at facilities owned, operated, or directed by the applicant; and

(B) the credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs.

4.5.4 the extent to which the facility will continue to provide appropriate access with respect to traditionally underserved populations as evidenced by:

(A) In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, both within and outside of Rhode Island, the demonstrated record of that person(s) with respect to access of traditionally under served populations to its health care facilities; and

(B) The proposed immediate and long term plans of the applicant to ensure adequate and appropriate access to the programs and health care services to be provided by the health care facility.

4.5.5 in consideration of the proposed continuation or termination of emergency, primary care and/or other core health care services by the facility:

(A) The effect(s) of such continuation or termination on access to safe and adequate treatment of individuals, including but not limited to traditionally underserved populations.

4.5.6 And in cases where the application involves a merger, consolidation or otherwise legal affiliation of two or more health care facilities, the proposed immediate and long term plans of such health care facilities with respect to the health care programs to be offered and health care services to be provided by such health care facilities as a result of the merger, consolidation or otherwise legal affiliation.

4.6 Subsequent to reviews conducted under sections 4.4 and 4.5 of these regulations, the issuance of a license by the licensing agency may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in section 23-17-3 of the Rhode Island General Laws, as amended, or to the review criteria set forth in section 4.5 herein. This shall not limit the authority of the licensing agency to require correction of conditions or defects which existed prior to the proposed change of owner, operator, or lessee and of which notice had been given to the facility by the licensing agency.

4.7 Any new hospital licensee shall meet the statewide community standard for the provision of charity care as a condition of initial and continued licensure, pursuant to sections 8.7 and 8.8 herein.

4.8 Those entities engaged in a hospital conversion shall be subject to the provisions of the *Rules and Regulations Pertaining to Hospital Conversions (R23-17.14-HCA)* promulgated by the Department. Nothing in the rules and regulations herein should be construed to be inconsistent with the *Rules and Regulations Pertaining to Hospital Conversions (R23-17.14-HCA).*

Section 5.0 ***Capacity & Classification***

5.1 Each license shall be issued for the specified licensed bed capacity of the hospital. No hospital shall have more inpatients than the number of beds for which it is licensed, except in cases of short term seasonal fluctuations, local epidemics, or multiple casualty emergencies.

5.1.1 The number of women in active labor admitted at any point in time to the birth center service shall be no greater than the number of birth rooms in the center.

Section 6.0 ***Inspections***

6.1 The licensing agency shall make, or cause to be made, such inspections and investigations as it deems necessary in accordance with section 23-17-10 of reference 22 and the regulations herein.

6.2 Every hospital shall be given prompt notice by the licensing agency of all deficiencies reported as a result of an inspection or investigation.

6.3 Written reports and recommendations of inspections shall be maintained on file in each hospital for a period of no less than three (3) years.

Section 7.0 ***Denial, Suspension, Revocation of License, Curtailment of Activities or Cessation of Operation***

7.1 The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any hospital which: (1) has failed to comply with the rules and regulations pertaining to licensing of hospitals; and (2) has failed to comply with the provisions of reference 22.

7.1.1 Lists of deficiencies noted in inspections conducted in accordance with section 6.0 herein shall be maintained on file in the licensing agency and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or curtail activities of a hospital.

7.2 Where the licensing agency deems that operation of a hospital results in undue hardship to patients as a result of deficiencies, the licensing agency is authorized to deny licensure to facilities not previously licensed, or to suspend for a stipulated period of time or revoke the license of a hospital already licensed or curtail activities of the hospital.

7.3 Whenever an action shall be proposed to deny, suspend or revoke a hospital license, or curtail its activities, the licensing agency shall notify the hospital by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with section 23-17-8 of reference 22 and section 42-35-9 of reference 1.

7.3.1 However, if the licensing agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with section 23-1-21 of the General Laws of Rhode Island, as amended, and in accordance with section 42-35-14(c) of reference 1.

7.4 The appropriate state and federal placement and reimbursement agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation of license or curtailment of activities.

7.5 A license shall immediately become void and shall be returned to the licensing agency whenever the hospital ceases delivering patient care.

PART II *ORGANIZATION & MANAGEMENT*

Section 8.0 *Governing Body*

8.1 Each hospital shall have an organized governing body or other legal authority, responsible for: (1) the management and control of the operation of the hospital; and (2) the conformity of the hospital with all federal, state and local laws and regulations relating to fire, safety, sanitation, communicable and reportable diseases; and (3) other relevant health and safety requirements and with all rules and regulations herein.

8.2 The governing body shall define the population and communities to be served and the scope of services to be provided.

8.2.1 The governing body, through the chief executive officer, shall provide for institutional planning to meet the health needs of the community, in accordance with section 23-17-10 of reference 22.

8.3 The governing body, through its chief executive officer, shall provide appropriate resources and personnel, and shall determine the qualifications of personnel as required herein, considering such factors as education, training, experience, board certification, eligibility to sit for examination of specialty board, evidence of current professional practice and licensure as may be required by law or regulation and such other relevant factor(s) as may be deemed necessary to meet the needs of the patients as well as the health needs of the community.

8.4 The governing body shall adopt and maintain written by-laws, rules and regulations in accordance with legal requirements and with its defined community responsibility, identifying the purpose of the hospital and the means of fulfilling them. A copy of said by-laws, rules and regulations including amendments or revisions thereto, shall be filed with the licensing agency.

8.4.1 Each hospital shall provide the licensing agency written notice of any changes to the hospital's corporate documents, including, but not limited to: charters/articles of incorporation and by-laws, and their equivalents for partnerships and limited liability corporations {LLCs}, immediately but no more than thirty (30) days of making such change. Materials provided shall be deemed to be public records.

8.4.2 Each hospital shall provide the licensing agency written notice of any changes to the corporate documents of any entity that owns, operates, and/or controls the licensed hospital, including, but not limited to: charters/articles of incorporation and by-laws, and their equivalents for partnerships and limited liability corporations {LLCs}, immediately but no more than thirty (30) days of making such change. Materials provided shall be deemed to be public records.

8.5 The by-laws, rules and regulations shall include:

a) a statement of purpose;

b) a statement of qualifications for membership and method of selecting members of the governing body;

c) provisions for the establishment, selection and term of office of committee members and officers;

d) a description of the functions and duties of the governing body, officers, and committees;

e) specifications for the frequency of meetings, attendance requirements, provisions for the order of business and the maintenance of written minutes;

f) a statement of the authority and responsibility delegated to the chief executive officer and to the medical staff;

g) provision for the selection and appointment of medical staff and the granting of clinical privileges. Such provisions shall include the appointment of a credentialing committee that shall include advance practice clinicians.

Physician Contracts

i) Pursuant to section 23-17-53 of the Rhode Island General Laws, as amended, a hospital, by contract or otherwise, may not refuse or fail to grant or renew medical staff membership or, staff privileges, or condition or otherwise limit or restrict staff privileges, based in whole or in part on the fact that the physician or a partner, associate, or employee of the physician is providing medical or health care services at a different hospital, hospital system or on behalf of a health plan; provided, however, that a hospital may condition or otherwise limit or restrict staff privileges for reasons related to the availability of limited resources as determined in advance by the hospital's governing body. Nor shall a hospital by contract, or otherwise limit a physician's participation or staff privileges or the participation or staff privileges of a partner, associate, or employee of the physician at a different hospital, hospital system or health plan.

ii) This section does not prevent a hospital from entering into contracts with physicians to ensure physician availability and coverage at the hospital or to comply with regulatory requirements or quality of care standards established by the governing body of the hospital, if contracts, requirements or standards do not require that a physician join, participate in or contract with a physician-hospital organization or similar organization as a condition of the grant or continuation of staff privileges at the hospital.

iii) This section does not prevent the governing body of a hospital from limiting the number of physicians granted medical staff membership or privileges at the hospital based on a medical staff development plan that is unrelated to a physician or a partner, associate, or employee of a physician having medical staff membership or privileges at another hospital or hospital system; or

iv) A contract provision that violates this section shall be void and of no force and effect.

h) provision for the approval of the medical staff by-laws, rules and regulations;

i) provision of guidelines for the relationships among the governing body, the chief executive officer, the medical staff and the community;

j) a policy statement concerning the development and implementation of short and long range plans in accordance with reference 22;

k) a policy statement concerning the publication of an annual report, including a certified financial statement;

l) a policy statement relating to conflict of interest on the part of members of the governing body, medical staff and employees who may influence corporate decisions;

m) provision that contracts with outside providers of services be restricted to those which comply with federal, state and local laws and the regulations herein; and

n) a policy statement relating to the protection of any physician or any other person or employee for non-participation in abortion or sterilization procedures in accordance with section 23-17-11 of reference 22.

8.6 The governing body or other appropriate authority of a hospital is authorized to suspend, deny, revoke or curtail staff privileges of any staff member for good cause in accordance with section 23-17-21 of reference 22.

Statewide Standard for the Provision of Charity Care, Uncompensated Care, and Community Benefits

8.7 Hospital charity care, uncompensated care, and community benefits standards shall be consistent with the requirements provided in the *Rules and Regulations Pertaining to Hospital Conversions (R23-17.14-HCA)* (See reference 56 herein).

Section 9.0 ***Quality Improvement***

9.1 The governing body shall ensure that there is an effective, ongoing, hospital-wide quality improvement program to evaluate the provision of patient care.

9.2 The organized hospital-wide quality improvement program shall be ongoing and shall have a written plan of implementation. The written quality improvement plan shall include at least the following:

a) program objectives;

b) organization(s) involved;

c) oversight responsibility (e.g., reports to the governing body);

d) hospital-wide scope;

e) program administration and coordination;

f) involvement of all patient care disciplines/services;

g) methodology for monitoring and evaluating quality of care;

h) priority setting and problem resolution;

i) determination of the effectiveness of action(s) taken;

j) documentation of the quality improvement plan review.

9.3 All patient care services, including services rendered by a contractor, shall be evaluated.

9.4 Nosocomial infections and medication therapy shall be evaluated.

9.5 All medical and surgical services performed in the hospital shall be evaluated for appropriateness in diagnosis and treatment. The evaluation shall include peer review of individual cases. The hospital shall maintain records of peer reviews, documenting the case(s) reviewed, focus of each review, findings, conclusions, any actions taken, and any follow-up on actions taken.

9.6 The hospital shall take and document appropriate remedial action to address problems identified through the quality improvement program. The outcome(s) of the remedial action shall be documented.

Section 10.0 ***Chief Executive Officer***

10.1 The chief executive officer shall be directly responsible to the governing body for the management and operation of the hospital and shall provide liaison between the governing body and the medical staff.

Section 11.0 ***Medical Staff***

11.1 Each hospital shall have an organized medical staff responsible for the quality of medical services and accountable to the governing body of the hospital.

11.2 The medical staff shall be responsible for its organized governance and for all medical care provided to patients.

11.3 The medical staff shall maintain standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.

11.4 The medical staff, subject to the approval of the governing body of the hospital, shall adopt by-laws incorporating details of its general powers, duties, and responsibilities including:

a) methods of selection, election or appointment of all officers and other executive committee members and officers;

b) provisions for the selection and appointment of officers of departments or services specifying required qualifications;

c) the type, purpose, composition and organization of standing committees;

d) frequency and requirements for attendance at staff departmental meetings;

e) an appeal mechanism for denial of staff appointments, reappointments and privileges;

f) delineation of clinical privileges of non-physician practitioners;

g) designation of personnel qualified to prescribe or administer drugs;

h) requirements regarding medical records;

i) a mechanism for utilization and medical care review;

j) such provisions as shall be required by hospital or governmental rules and regulations; and

k) provisions for a program permitting selected individuals other than physicians or other licensed, registered or certified personnel to perform extended, defined patient care functions. Said functions shall not otherwise require a license, certification or registration by state law. Such program shall include written systems of credentials review, selection, training, formal authorization of specific functions and maintenance of a current register.

11.5 A copy of approved medical staff by-laws and regulations and revisions thereto, shall be submitted to the licensing agency.

Section 12.0 ***Organization***

12.1 Each hospital shall maintain clearly written definitions of its organization, authority, responsibility and relationships.

12.2 Each hospital department and service shall maintain:

a) clearly written definitions of its organization, authority, responsibility and relationships;

b) written patient care policies and procedures; and

c) written provision for systematic evaluation of programs and services.

12.3 Every licensed hospital and its insurance carrier shall cooperatively, as part of their administrative function, establish an internal risk management program in accordance with the requirements of section 23-17-22 of reference 22.

12.4 All hospitals shall comply with the requirements of Chapter 23-18.6 of the General Laws and Rhode Island Health Department *Rules and Regulations Relating to Procurement of Anatomical Gifts from Persons with Unknown Intent (R23-18.6 ANGFT)* by establishing protocols related to anatomical gifts and all other relevant requirements.

12.5 Any hospital that utilizes latex gloves shall do so in accordance with the provisions of the *Rules and Regulations Pertaining to the Use of Latex Gloves by Health Care Workers, in*

Licensed Health Care Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department promulgated by the Department of Health.

Section 13.0 ***Personnel***

13.1 The hospital shall maintain a sufficient number of qualified personnel to provide effective patient care and all other related services.

13.2 There shall be written personnel policies and procedures which shall be made available to personnel.

13.3 Provisions shall be made for orientation and ongoing education programs for all personnel. There shall be written evidence that staff demonstrate competencies necessary to work in specific areas and/or with specific patient populations.

13.4 There shall be a job description for each position which delineates the qualifications, duties, authority and responsibilities inherent in each position.

a) For those authorized to perform defined functions in accordance with section 11.4(k) herein, a job description delineating qualifications, duties, authority and responsibilities shall be provided.

b) For every individual within the hospital who is licensed, certified or registered by the state of Rhode Island, a mechanism shall be in place to verify currency of licensure electronically via the Department's licensure database.

13.5 There shall be work performance evaluation programs with appropriate records maintained.

13.6 Non-employee staff (including but not limited to volunteers, per diem staff and contractees) who are working in the hospital must adhere to policies and procedures of the hospital. The hospital must provide for adequate orientation, supervision and evaluation of the activities of non-employee staff.

13.7 If the hospital does not employ personnel to render required services, or obtains services from an outside source, arrangements for such services shall be made through written agreements or contracts.

a) The responsibilities, functions, objectives, terms of agreement, financial arrangements, charges and other pertinent requirements shall be clearly delineated in the terms of any contract negotiated by the hospital.

b) All contracts or agreements negotiated by the hospital shall be consistent with the provisions established in accordance with sections 8.5 (l) (m) herein.

13.8 Pursuant to section 23-17-52 of the Rhode Island General Laws, as amended, any hospital licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended, shall provide to all patients and staff, through posted notices in conspicuous places throughout the hospital, the current Office of Facilities Regulation telephone number to call with concerns. Such notices shall be written in English and, at a minimum, the three most common

languages used by patients served by each hospital as determined by such hospital, and shall include the internationally-recognized symbol for sign language {including a relay number for access by hearing/speech impaired (TTY)}.

13.9 In accordance with section 23-17-47 of the Rhode Island General Laws, as amended, a health care facility shall require all persons, including students, who examine, observe or treat a patient or resident of such facility to wear a photo identification badge which states, in a reasonably legible manner, the first name, licensure registration status, if any, and staff position of such person.. For hospital designated interpreters and bilingual clinicians, include fluency in sign languages or language other than English, if any, and staff position of such person on the badge. This badge shall be worn in a manner that makes the badge easily seen and read by the patient or visitor.

Health Screening

13.10 Upon hire and prior to delivering services, pre-employment health screenings shall be required for each individual who has or may have direct contact with a patient in the hospital. Such health screening shall be conducted in accordance with *the Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW)* promulgated by the Department of Health.

Safe Patient Handling

13.11 Each licensed hospital shall comply with the following as a condition of licensure:

a) Each licensed hospital shall establish a safe patient handling committee, which shall be chaired by a professional nurse or other appropriate licensed health care professional. A hospital may utilize any appropriately configured committee to perform the responsibilities of this section. At least half of the members of the committee shall be hourly, non-managerial employees who provide direct patient care.

b) Each licensed hospital shall develop a written safe patient handling program, with input from the safe patient handling committee, to prevent musculoskeletal disorders among health care workers and injuries to patients. As part of this program, each licensed health care facility shall:

(i) Implement a safe patient handling policy for all shifts and units of the facility that will achieve the maximum reasonable reduction of manual lifting, transferring, and repositioning of all or most of a patient's weight, except in emergency, life-threatening, or otherwise exceptional circumstances;

(ii) Conduct a patient handling hazard assessment. This assessment should consider such variables as patient-handling tasks, types of nursing units, patient populations, and the physical environment of patient care areas;

(iii) Develop a process to identify the appropriate use of the safe patient handling policy based on the patient's physical and mental condition, the patient's choice, and the availability of lifting equipment or lift teams. The policy shall include a means to address circumstances under which it would be medically

contraindicated to use lifting or transfer aids or assistive devices for particular patients;

(iv) Designate and train a registered nurse or other appropriate licensed health care professional to serve as an expert resource, and train all clinical staff on safe patient handling policies, equipment, and devices before implementation, and at least annually or as changes are made to the safe patient handling policies, equipment and/or devices being used;

(v) Conduct an annual performance evaluation of the safe patient handling with the results of the evaluation reported to the safe patient handling committee or other appropriately designated committee. The evaluation shall determine the extent to which implementation of the program has resulted in a reduction in musculoskeletal disorder claims and days of lost work attributable to musculoskeletal disorder caused by patient handling, and include recommendations to increase the program's effectiveness; and

(vi) Submit an annual report to the safe patient handling committee of the facility, which shall be made available to the public upon request, on activities related to the identification, assessment, development, and evaluation of strategies to control risk of injury to patients, nurses and other health care workers associated with the lifting, transferring, repositioning, or movement of a patient.

c) Nothing in this section precludes lift team members from performing other duties as assigned during their shift.

d) An employee may, in accordance with established facility protocols, report to the committee, as soon as possible, after being required to perform a patient handling activity that he/she believes in good faith exposed the patient and/or employee to an unacceptable risk of injury. Such employee reporting shall not be cause for discipline or be subject to other adverse consequences by his/her employer. These reportable incidents shall be included in the facility's annual performance evaluation.

Overtime Requirement

13.12 All hospitals shall be in compliance with the provisions of Chapter 23-17.20 of the Rhode Island General Laws, as amended, of reference 82 herein ("Health Care Facilities Staffing").

Credentialing of Advanced Practice Clinicians

13.13 All advanced practice clinicians shall be appropriately credentialed by the hospital.

13.14 All advanced practice clinicians shall be credentialed through the medical staff appointment process and shall be subject to continuing quality assurance review by medical staff mechanisms.

13.15 The medical staff shall delineate clinical privileges granted to advanced practice clinicians and shall communicate same in accordance with hospital policies.

13.16 The hospital shall document clinical privileges granted to advance practice clinicians. These documents shall be reviewed no less than every two (2) years by the medical staff so as to reflect current operations within the hospital and the continued competency of the advanced practice clinician.

Section 14.0 ***Professional Library***

14.1 The hospital shall provide appropriate library services for the professional and technical needs of hospital personnel including:

a) current books, periodicals and other pertinent materials;

b) appropriate computer resources for literature search and retrieval;

c) adequate facilities; and

d) adequate personnel to maintain the library service.

Section 15.0 ***Rights of Patients***

15.1 Every hospital shall observe the following standards with respect to each patient who is admitted to its facility as enumerated in section 23-17-19.1, "Rights of Patients" and section 40.1-5-5, "Admission of Patients Generally--Rights of Patients" of the General Laws of Rhode Island, as amended.

15.1.1 The hospital shall inform the patient of the right to include a written durable power of attorney and/or living will into his/her medical record.

15.2 A copy of the Rights of Patients shall be given to each patient or his/her representative upon admission and shall be posted in a conspicuous place on the premises.

Patient Visitation Rights

15.3 All health care providers, as licensed under the provisions of Chapter 29 or 37 of Title 5 and all health care facilities, as defined in section 23-17-2(5) of the Rhode Island General Laws, as amended, shall be required to note in their patients' permanent medical records, the name of individual(s) not legally related by blood or marriage to the patient, who the patient wishes to be considered as immediate family member(s), for the purpose of granting extended visitation rights to said individual(s), so said individual(s) may visit the patient while he or she is receiving inpatient health care services in a health care facility.

15.3.1 The patient visitation provisions set forth in this section shall not prohibit a hospital from establishing reasonable policies related to the number of visitors each patient may have at any one time.

15.4 A patient choosing to designate said individual(s) as immediate family members for the purpose of extending visitation rights may choose up to five (5) individuals and do so either verbally or in writing. This designation shall be made only by the patient and can be initiated and/or rescinded by the patient at any time, either prior to, during, or subsequent to an inpatient stay at the health care facility.

15.5 The full names of individual(s) so designated, along with their relationship to the patient, shall be recorded in the patient's permanent medical records, both at the inpatient health care facility and with the patient's primary care physician.

15.6 In the event the patient has not had the opportunity to have said designation recorded in his or her medical records, a signed statement in the patient's own handwriting attesting to the designation of said individual(s) as an immediate family member for the purpose of extending visitation right during the provision of health care services in an inpatient health care facility, along with their relationship to said individual(s) shall meet all the requirements of this section. The patient's signature on said signed statement shall be witnessed by two individuals, neither of whom can be the designated individual(s). In the event such signed statement is not available, those designated as agents on a durable power of attorney for health care form shall be allowed visitation privileges.

15.7 This section shall not be construed to prohibit legally recognized members of the patient's family from visiting the patient if they have not been so designated through the provisions of this section. No patient shall be required to designate individual(s) under the provisions of this section.

Concern Line

15.8 Pursuant to section 23-17-52 of the Rhode Island General Laws, as amended, any hospital licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended, shall provide to all patients and staff, through posted notices in conspicuous places throughout the hospital, the current Office of Facilities Regulation telephone number to call with concerns.

Such notices shall be written in English and, at a minimum, the three most common languages used by patients and staff served by each hospital as determined by such hospital, and shall include the internationally-recognized symbol for sign language {including a relay number for access by hearing/speech impaired (TTY)}.

Section 16.0 ***Research Involving Human Subjects***

16.1 A hospital that conducts research involving human subjects shall comply with all applicable state and federal laws, rules and regulations, including any required review and approval by an Institutional Review Board (IRB). The hospital shall have written polices and procedures governing research activities.

16.2 If the hospital conducts research involving human subjects who are not otherwise patients of the hospital (i.e., not receiving inpatient, outpatient, or emergency services) the following requirements shall be met:

a) There shall be a written protocol for each research study which, at a minimum, describes the nature and purpose of the study, the procedures to be utilized, the extent and type of assessment/testing of subjects, the risks of participation, the content of and subject's access to records to be maintained, and provisions regarding confidentiality and disclosure of information.

b) Each subject shall be advised of the items listed in section 16.2(a) (above), as well as

his/her rights and responsibilities, and shall agree to participate in the research study. The use of written consent shall apply to all research participants, except those identified in the federal regulations that guide IRBs in the protection of human subjects (45 CFR 46.116-46.117) (for example, minimal-risk survey studies), and where the requirement for written consent has been explicitly waived by the hospital's IRB. Also, written consent shall not be required for studies that are exempt from IRB review (45 CFR 46.101). Studies conducted using information abstracted from existing records in anonymous form shall not have a requirement of directly contacting individuals involved in the research.

(i) In accordance with section 23-17-19.1 (10) of the Rhode Island General Laws, as amended, except as otherwise provided in this subparagraph, if the health care facility proposes to use the patient in any human subjects research, it shall first thoroughly inform the patient of the proposal and offer the patient the right to refuse to participate in the project.

(ii) No facility shall be required to inform prospectively the patient of the proposal and the patient's right to refuse to participate when: (i) the facility's human subjects research involves the investigation of potentially lifesaving devices, medications and/or treatments and the patient is unable to grant consent due to a life-threatening situation and consent is not available from the agent pursuant to Chapter 23-4.10 of the General Laws or the patient's decision maker if an agent has not been designated or an applicable advanced directive has not been executed by the patient; and (ii) the facility's institutional review board approves the human subjects research pursuant to the requirements of 21 CFR Part 50 and/or 45 CFR Part 46 (relating to the informed consent of human subjects).

(iii) Any health care facility engaging in research pursuant to the requirements of this section shall file a copy of the relevant research protocol with the Department, which filing shall be publicly available.

c) Hospital standards and procedures shall be observed in all clinical activities involving research subjects (e.g., phlebotomy or other specimen collection, EKG, etc.) unless deviation from standard procedures is integral to the research, in which case this shall be described in the written study protocol.

d) There shall be written procedures pertaining to the control, accountability, security, administration, and maintenance of records of receipt and disposition of all drugs and biologicals utilized in each research study.

e) If research staff become aware of any clinical condition/concern which may warrant further assessment or treatment, he/she shall promptly notify the subject and advise follow-up with a health care provider.

f) Records regarding a subject are exempt from the requirements of section 27.0 herein (medical records) but shall be maintained in conformance to the written study protocol. Subject records, either original or accurate reproduction, shall be maintained for a minimum of five (5) years.

g) In addition to the requirements of section 13.0 herein (personnel), there shall be evidence that all staff participating in a research study have received training in the specific protocols to be applied.

h) Research activities involving human subjects who are not otherwise patients of the hospital shall be exempt from the requirements of section 9.0 herein (quality improvement). However, there shall be a quality assurance program in effect to ensure conformance to the written study protocols. Quality assurance activities may be documented in the study protocol.

Section 17.0 ***Uniform Reporting System***

17.1 Each hospital shall establish and maintain records and data in such a manner as to make uniform the system of periodic reporting. The manner in which the requirements of this regulation may be met shall be prescribed from time to time in directives promulgated by the Director with the advice of the Health Services Council.

17.2 Each hospital shall report to the licensing agency detailed financial and statistical data pertaining to its operations, services, and facilities. Such reports shall be made at such intervals and by such dates as determined by the Director and shall include but not be limited to the following:

a) utilization of inpatient and outpatient hospital facility and services;

b) unit cost of hospital services;

c) charges for rooms and services;

d) audited financial statements for both hospital and any parent corporation/foundation; and

e) quality of hospital care.

17.3 The licensing agency is authorized to make the reported data available to any state agency concerned with or exercising jurisdiction over the reimbursement or utilization of hospitals.

17.4 The directives promulgated by the Director pursuant to these regulations shall be sent to each hospital to which they apply. Such directives shall prescribe the form and manner in which the financial and statistical data required shall be furnished to the licensing agency.

Inpatient, Emergency Department, and Observation Unit Data

17.5 All licensed hospitals in this state shall be subject to the uniform reporting of financial and statistical data on hospital inpatient services, emergency department services, and observation unit services in accordance with the technical and data specifications contained in references 77, 78, and 79 herein. The provisions of this section shall take effect October 1, 2004.

17.5.1 Data submitted in accordance with section 17.5 above shall contain only the medical record number or the hospital assigned number and no other patient identifying information to ensure anonymity of the reported data.

17.5.2 The Department shall provide licensed hospitals with no less than a twenty (20) day comment period after issuing or changing the reporting requirements.

17.5.2.1 Licensed hospitals shall have a period of at least ninety (90) days after the comment period to comply with new or changed reporting requirements.

PART III *PATIENT CARE SERVICES*

Section 18.0 *Admission, Transfer & Discharge*

18.1 Each hospital shall have written admission, transfer and discharge policies and procedures pertaining to at least the following:

a) types of clinical conditions acceptable for admission to specific levels of care and appropriate clinical departments or services;

b) informing and offering advance directives to all patients upon admission;

c) constraints imposed by limitations of services, physical facilities or staff coverage;

d) emergency admissions;

e) requirements for informed consent signed by patient or legal representatives for diagnostic and treatment procedures;

f) internal transfer of patients from one level or type of care to another;

g) discharge and termination of services; and

h) provisions for a mechanism for recording, transmitting patient-specific information to other health care providers and receiving information essential to the continuity of patient care. (This mechanism shall include the required use of the Department's Continuity of Care form. See also section 18.3 (c)(iii) herein).

18.2 In addition to the above policies in section 18.1 each hospital shall adopt the following:

a) no person shall be denied admission to the hospital because of race, color, religion, ancestry, sexual orientation, or national origin;

b) every patient admitted to the hospital shall be and remain under the care of a member of the medical staff as specified under the by-laws;

c) no suspected or actually infected non-obstetric patient shall be admitted to the obstetric department or unit;

d) transfer agreements or contracts shall clearly delineate responsibilities of parties involved; and

e) Pursuant to sections 23-17.14-15(3)(4) of the Rhode Island General Laws, as amended, not discourage persons who cannot afford to pay from seeking essential medical services; and not encourage persons who cannot afford to pay to seek essential medical services from other providers.

Discharge Planning

18.3 The hospital shall have a discharge planning process for all inpatients. Discharge planning policies and procedures must be in writing and shall include a mechanism for discharge planners to receive regular updates regarding new offerings of community programs and the complete range of current options available at discharge.

a) The hospital shall identify, at an early stage in hospitalization, all inpatients who are

likely to suffer adverse health consequences on discharge if there is no adequate discharge planning.

b) A discharge planning evaluation shall be provided to all inpatients identified in a) above, to other patients on patient request, the request of the person acting on the patient's behalf, or upon the request of the physician.

i) The evaluation shall be timely to avoid unnecessary delays in discharge and must be part of the patient's medical record.

ii) The evaluation shall include a needs assessment, the patient's capacity for self-care, and the availability of post-hospital services to meet the needs of the patient.

iii) A registered nurse or social worker shall develop or supervise the development of the evaluation.

iv) The results of the evaluation shall be discussed with the patient or the individual acting on the patient's behalf.

v) The evaluation shall be used to establish an appropriate discharge plan.

c) A registered nurse or social worker shall develop or supervise the development of a discharge plan if the discharge planning evaluation indicates the need for a discharge plan.

i) The hospital shall arrange for implementation of the discharge plan.

ii) The hospital shall transfer or refer inpatients and outpatients to appropriate facilities, agencies, or outpatient services, as needed, for follow-up care.

iii) Designated hospital personnel shall complete the "Continuity of Care" form approved by the Department for each patient who is discharged to another health care facility licensed under the provisions of Chapter 23-17 of the Rhode Island General Laws, as amended (e.g., nursing facility). The Continuity of Care form and instructions for its use should be downloaded from the Department's website: www.healthri.org.

d) The hospital shall reassess its discharge planning process on an on-going basis. The reassessment shall include a review of discharge plans, as well as a review of patients who were discharged without plans, to ensure that the process is responsive to discharge needs.

Financial Interest Disclosure

18.4 Any health care facility licensed pursuant to Chapter 23-17 of the Rhode Island General Laws, as amended, which refers clients to another such licensed health care facility or to a residential care/assisted living facility licensed pursuant to Chapter 23-17.4 of the Rhode Island General Laws, as amended, or to a certified adult day care program in which the referring entity has a financial interest shall, at the time a referral is made, disclose in writing the following information to the client: (1) that the referring entity has a financial interest in the facility or provider to which the referral is being made; (2) that the client has the option

of seeking care from a different facility or provider which is also licensed and/or certified by the state to provide similar services to the client.

18.5 The referring entity shall also offer the client a written list prepared by the Department of Health of all such alternative licensed and/or certified facilities or providers. Said written list may be obtained by contacting:

Rhode Island Department of Health, Office of Facilities Regulation
3 Capitol Hill, Room 306
Providence, RI 02908
401.222.2566

18.6 Non-compliance with sections 18.4 and 18.5 (above) shall constitute grounds to revoke, suspend or otherwise discipline the licensee or to deny an application for licensure by the Director, or may result in imposition of an administrative penalty in accordance with Chapter 23-17.10 of the Rhode Island General Laws, as amended.

Section 19.0 ***Patient Care Management***

19.1 A mechanism shall be established for the periodic review and revision of patient care policies and procedures.

19.2 There shall be evidence that medical, nursing and other services are provided under an integrated written plan of care for each patient. Written care plans shall identify problems, goals, and interventions. Goals shall be measurable.

19.3 All orders for medications or treatments must be in writing. An order is considered to be in writing if: (1) it is written and signed by a lawfully authorized person; or (2) it is dictated to and transcribed by a registered nurse or other appropriately licensed person onto the order form. Additionally, the registered nurse or other appropriately licensed person must: (1) date the order and identify the telephone or verbal order by the name and title of the authorized individual who gave the order; and (2) sign the order entry with his/her own name and title. All verbal or telephone orders must be appropriately signed by a practitioner involved in the care of the patient no later than the end of the next calendar day.

19.3.1 Hospitals may implement a standing orders program authorizing licensed nurses and other licensed health care professionals acting within their scopes of practice to administer influenza and/or pneumococcal vaccines without a physician signature in accordance with an institution-approved or physician-approved protocol. The standing orders shall be in accordance with the most current national guidelines issued by the Advisory Council on Immunization Practices (ACIP).

19.4 There shall be a written policy for appropriate minimum, specific testing for all surgical inpatients and for all patients who are undergoing specific procedures requiring anesthesia in the inpatient and outpatient settings.

19.5 The hospital shall assure that drugs and biologicals are only administered by appropriately licensed professionals, including but not limited to, physicians, nurses, or physician

assistants. Medication administration technicians shall not administer drugs or biologicals under any circumstances.

19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care.

19.7 ***Medical Restraints***: In acute medical and pre/post-surgical care, a patient shall be free from physical and chemical restraint that is not medically necessary. A restraint shall only be used if needed to improve the patient's well-being and only if less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.

Behavioral Restraints: A patient shall be free from seclusion or restraint imposed as a means of coercion, discipline, convenience or retaliation by staff. Seclusion or restraint employed for behavior management shall only be used in emergency situations if needed to ensure the patient's or other's physical safety and less restrictive interventions have been determined to be ineffective.

19.7.1 Restraints/seclusion use shall be prescribed in writing and signed by a physician or other licensed practitioner acting within his/her scope of practice and permitted by the hospital to order restraints/seclusion. The type and duration of restraints/seclusion shall be specified. Standing or "on an as needed basis" (i.e., PRN) orders shall not be permitted.

19.7.2 Restraints/seclusion, if used, shall be addressed in the written treatment plan for the patient.

19.7.3 Restraints/seclusion use shall be based on an assessment of the patient, implemented in the least restrictive manner possible, implemented in accordance with safe and appropriate restraining techniques, and discontinued at the earliest possible time.

19.7.4 The condition of a restrained/secluded patient shall be continually assessed, monitored, and reevaluated.

Pain Assessment

19.8 All health care providers licensed by this state to provide health care services and all health care facilities licensed under Chapter 23-17 of the Rhode Island General Laws, as amended, shall assess patient pain in accordance with the requirements of the *Rules and Regulations Related to Pain Assessment* (*R5-37.6-PAIN*) promulgated by the Department.

Section 20.0 ***Provision of Interpreter Services***

20.1 Every hospital shall, as a condition of initial or continued licensure, provide a qualified interpreter, if an appropriate bilingual clinician is not available to translate, in connection with all services provided to every non-English speaker who is a patient or seeks appropriate care and treatment and is not accompanied or represented by an appropriate qualified interpreter or a qualified sign language interpreter who has attained at least sixteen (16) years of age

20.2 No later than 1 July 2002, each hospital shall develop, establish and maintain a formal plan for the provision of language interpretation with respect to the provision of hospital services in all licensed settings.

20.2.1 Each hospital shall establish criteria for the qualification of interpreters. In addition to fluency in a language other than English, interpreters shall have demonstrated competency in the following topics, at a minimum: (i) the appropriate role of a medical interpreter; (ii) the confidentiality of health care information; (iii) the ethical issues involved in serving as a medical interpreter; (iv) common medical terminology; and (v), relevant hospital policies and procedures.

20.2.2 Each hospital shall review the qualifications of and designate individuals as interpreters in specific languages. Such reviews and designations shall be documented.

20.2.3 Each hospital shall establish criteria for the qualification of bilingual clinicians. In addition to being bilingual, clinicians shall have knowledge of the following topics: (i) the appropriate role of a medical interpreter; (ii) the ethical issues involved in serving as a medical interpreter; (iii) common medical terminology; and (iv) relevant hospital policies and procedures.

20.2.4 Each hospital, for the purposes of providing interpretive services, shall review the qualifications of and designate clinicians as bilingual in specific languages. Such reviews and designations shall be documented.

20.2.5 Each hospital may also contract with appropriate off-site interpreter service providers for the provision of qualified interpreter services provided that hospital has received the prior written approval of such arrangements from the state agency.

20.3 Each hospital shall post a multi-lingual notice in conspicuous places setting forth the requirements of section 20.1 above in English, include the internationally-recognized symbol for sign language {including a relay number for access by hearing/speech impaired (TTY)} and include, at minimum, three (3) most common foreign languages used by the hospital as determined by the hospital.

Section 21.0 ***Central Service Functions***

21.1 Hospitals with central service functions shall operate, under the supervision of a qualified person, a central service for the processing, sterilization, storing and dispensing of clean and sterile supplies and equipment.

21.2 Adequate facilities shall be provided for the cleaning, preparation, sterilization, aeration, storage and dispensing of supplies and equipment for patient care.

21.3 Areas for the processing of clean and dirty supplies and equipment shall be separated by physical barriers.

21.4 Written procedures shall be established for all central service functions including:

a) procedures for all sterilization and for monitoring the effectiveness thereof; and

b) appropriate disposal of wastes and contaminated supplies; and

c) compliance with the provisions of reference 9.

21.4.1 Such procedures shall be subject to the approval of a multidisciplinary hospital group.

21.5 Reports of bacteriological tests and dated recordings of thermometer charts and inspection records shall be maintained in accordance with written procedures.

21.6 Central service procedures shall apply wherever sterilization is performed.

Section 22.0 ***Dietary Service***

22.1 Each facility shall maintain a dietary service directed by a full-time person qualified by training and experience in organization and administration of food service.

22.2 Each hospital shall have at least one Registered Dietitian, licensed by the state, to direct nutritional aspects of patient care and to advise on food preparation and service.

22.3 Adequate space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and service of food and other related aspects of the food service operation.

22.3.1 Any construction, addition, alterations affecting food service operations shall be in conformity with the requirements of section 23-1-31, "Approval of Construction by Director" of the Rhode Island General Laws of reference 29.

22.4 Each hospital food service operation shall comply with the applicable standards of reference 2.

22.5 Foods shall be prepared by methods that conserve nutritive value, flavor and appearance.

22.6 Foods served shall be palatable, attractive and at proper temperature.

22.7 Written policies and procedures shall be established for dietary services, pertaining to but not limited to the following:

a) responsibilities and functions of personnel;

b) standards for nutritional care in accordance with reference 3;

c) identifying patients at nutritional risk;

d) precise delivery of patient's dietary order;

e) alterations or modifications to diet orders or schedules;

f) food purchasing, storage, preparation and service;

g) safety and sanitation relative to personnel and equipment;

h) ancillary dietary services, including food storage and preparation in satellite kitchens, and vending operations;

i) ice making in accordance with reference 4; and

j) standards for enteral nutritional care.

22.8 Any hospital engaged in processing, handling, or both, of frozen foods shall be subject to standards of reference 5.

22.9 There shall be a diet manual maintained by the dietary service which shall be reviewed, revised as necessary and approved by a multidisciplinary group at least every five (5) years and more often as necessary. Diets served to patients shall comply with the principles set forth in the diet manual.

22.10 All patient diets shall be ordered in writing by the physician.

22.11 Assessments, observations and information pertinent to dietetic treatment shall be recorded in the patient's medical record by the dietitian.

22.12 A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of these regulations.

Section 23.0 ***Disaster & Mass Casualty Program***

23.1 Each hospital shall develop and maintain a written disaster plan which shall include provisions for complete evacuation of the facility and for the timely care of casualties arising from both external and internal disasters based on the guidelines of reference 9.

23.2 The plan shall also include provisions for:

a) disaster-site triage and distribution of patients to ensure the most efficient use of available facilities and services;

b) a mechanism for physician identification as well as route access and entrance to the hospital; and

c) back-up or contingency plans to address internal systems, electronic disasters, including a backup system for an electronic medical record file system, and/or equipment failures.

23.3 The plan(s) shall be developed and coordinated with the appropriate state and local agencies and representatives concerned with emergency, safety, rescue and disaster preparedness.

23.4 The disaster plan shall be rehearsed at least twice a year preferably as part of a coordinated drill in which other community emergency services agencies participate with hospital, medical, administrative, nursing and other personnel.

23.5 Written reports and evaluation of all drills shall be maintained.

23.6 A copy of the plan(s) and any revision thereto shall be submitted to the licensing agency.

Section 24.0 ***Emergency Service***

24.1 Each hospital shall have a well defined plan for emergency services based on community need and on the capability of the hospital and its specialized supportive services.

a) The hospital plan for emergency services shall be developed in cooperation with representatives of community emergency medical service agencies or groups (e.g., emergency medical service councils).

b) Hospitals without an emergency department or service shall have written policies and procedures governing the handling of emergencies.

c) Pursuant to section 23-17-26 of reference 22, every hospital with an emergency medical care unit shall provide to every person prompt life saving medical treatment in an emergency:

(i) without discrimination based on economic status or source of payment; and

(ii) without delaying treatment for the purpose of prior discussion of source of payment;

unless such delays can be imposed without material risk to the health of the person.

24.2 Each hospital emergency department or service shall be organized to provide twenty-four (24) hour services with adequate professional and ancillary staff coverage to ensure that all persons are treated within a reasonable length of time, commensurate with the priority for treatment.

24.3 Every emergency department or service shall have a person qualified by training and experience in the department twenty-four (24) hours a day who shall determine the nature, level and urgency of care required of all persons seeking treatment and to categorize them accordingly, assuring that serious cases are accorded priority treatment. If such person is a non-physician, he or she shall serve under the supervision of the physician-in-charge and in accordance with policies and procedures acceptable to the medical staff and hospital administration.

24.4 Every hospital emergency department or service shall have a qualified member of the medical staff assigned as physician-in-charge or made responsible for the emergency medical services, to ensure that emergency patient care services meet the standards herein and for the coordination of physician coverage according to a plan established by the medical staff and approved by the governing authority.

24.5 At least one physician on duty in the emergency department of a general hospital shall be certified by the American Board of Emergency Medicine or the American Board of Osteopathic Emergency Medicine or shall be eligible to sit for examination of one of the aforementioned boards; or shall be Board certified or eligible in Family Practice, Internal Medicine or General Surgery with at least one (1) year of practice in emergency medicine; or those physicians who have practiced in an emergency department setting for at least seven

thousand (7,000) hours in sixty (60) months with two thousand (2,000) of said practice hours having been completed in the last twenty-four (24) months.

24.5.1 At least one physician on duty or immediately available "on call" in the emergency department of a psychiatric hospital shall be certified by the American Board of Psychiatry and Neurology or shall be eligible to sit for the examination of the aforementioned board.

24.6 Additional staff in the emergency department or service of a general hospital shall meet the following qualifications: a) a physician who is Board certified or eligible in Family Practice, Internal Medicine, General Surgery or Pediatrics; b) a physician with more than two (2) years of practice following full licensure; or c) in those hospitals having approved residency training programs, by residents with more than two (2) years of training in the specialties of internal medicine, surgery, pediatrics, and/or emergency medicine, when such emergency department training is part of their formal residency training program.

24.7 In addition, hospitals shall have available on call twenty-four (24) hours a day, physicians in specialties appropriate to the scope of services provided by the hospital.

24.8 A current roster of physicians, medical specialists or consultants on emergency call, including alternates, shall be kept posted at all times in the emergency department or service.

24.9 The staffing pattern of nursing and allied health personnel shall be consonant with the scope and complexity of the emergency services provided. No less than one registered nurse who has training and experience in emergency care shall be assigned to the emergency services at all times.

24.10 A continuing inservice education training program in emergency medical care, including prehospital care protocols and standing orders in accordance with the provisions of reference 42, shall be conducted for all categories of health personnel in the emergency department or service in accordance with section 13.0 herein.

24.11 There shall be written policies governing emergency patient care services, supported by appropriate procedure manuals and reference materials. The policies and procedures shall pertain to at least the following:

a) medical staff and obligation for emergency patient care in accordance with section 24.1(c) herein;

b) circumstances under which definitive care shall not be provided and procedures to be followed in referrals;

c) assignment of clinical privileges according to levels of professional competence;

d) procedures that may or may not be performed in the emergency department or service area;

e) handling of persons who are emotionally ill, under the influence of drugs or alcohol, dead on arrival, or other categories of special cases as determined necessary;

f) procedures for early transfer of severely ill or injured to special in-house treatment areas or to other facilities;

g) written instructions to be given for follow-up care and disposition of all cases;

h) notification of patient's personal physician and transmission of relevant reports;

i) disclosure of patient information in accordance with federal and state law;

j) communication with police, health authorities and emergency vehicle operators;

k) appropriate utilization of observation beds;

l) procurement of equipment and drugs; and

m) operation of the emergency department or service in times of disaster.

24.12 A list of poison antidotes and the telephone number of the Rhode Island Poison Control Center shall be available in the emergency department or service area.

24.13 The emergency service shall have necessary supportive services available on a twenty-four (24) hour basis. These services shall include, in accordance with the rules and regulations herein, anesthesia service (see section 37.0); clinical laboratory service with arterial blood gas analysis capability (see section 26.5); blood transfusion services (see section 26.9); pharmaceutical service (see section 31.1); radiology service including protocol to govern the interpretation by a radiologist, of diagnostic images produced by x-ray or other modalities, including a procedure for the prompt communication of the radiologist's interpretation (see section 32.1); and surgical service (see section 36.0).

24.14 Facilities, equipment, supplies and drugs for the reception, appraisal, examination, treatment and observation of emergency room patients shall be determined by the amount, type and extensiveness of services provided.

24.15 No less than the following special supplies and equipment shall be available and located within the general hospital emergency department or service:

a) oxygen;

b) electrocardiograph;

c) cardiac monitor and defibrillator with battery pack;

d) pacemaker;

e) central venous catheter set-up;

f) gastric lavage equipment;

g) suction device;

h) intravenous fluids and administration devices;

i) endotracheal intubation, pericardiocentesis, thoracostomy, and cricothyrotomy trays;

j) mechanical ventilator (readily available);

k) emergency obstetrical pack; and

l) pulse oximeter for measuring carboxyhemoglobin levels.

24.16 The emergency drug cart(s) and adjunctive emergency equipment shall be checked by an appropriate, designated individual at least once per shift to assure that all items required for immediate availability are actually contained in the cart and are in usable condition.

24.16.1 A signed record of such periodic inspections shall be maintained by the appropriate emergency department staff.

24.17 A medical record shall be maintained on every patient seeking emergency care. For each visit to the emergency service, the medical record shall contain documentation relating to the following:

a) patient identification (name, address, age and sex);

b) time and means of arrival;

c) pertinent medical history of the illness or injury and physical findings;

d) emergency care given before arrival;

e) diagnostic and therapeutic orders;

f) reports of procedures, tests, treatments and findings;

g) diagnostic impression;

h) conclusion at termination of evaluation/treatment, including final disposition of patient, condition on discharge or transfer, and any instructions given for follow-up care;

i) a patient's leaving against medical advice; and

j) origin of incoming patient and destination of patient at discharge.

k) the standardized Rhode Island EMS Ambulance Run Report ("run report") provided, prepared and signed by the licensed emergency medical technician who completed the form.

24.18 A mechanism shall be developed to include the emergency department record into the patient's medical record in accordance with section 27.3 herein.

24.19 Those hospitals which have provisions for Mobile Intensive Care Communications manned by technical personnel shall comply with the requirements of reference 6.

24.20 The standards of section 15.0 herein pertaining to "Rights of Patients" shall be observed for all patients treated in the emergency department or service. In addition, hospitals shall:

a) provide access to a physically separate room, office or chapel, wherein privacy can be guaranteed, for families when circumstances shall warrant (such room may have alternative uses); and

b) inform emergency service patients, by posting in an easily visible location, that the routine cost for use of the emergency service does not include additional professional

service charges except in the case where residents who perform the service are employed by the hospital.

Restocking of Municipal Ambulance Supplies

24.21 Pursuant to section 23-4.1-7.1 of the Rhode Island General Laws, as amended, every hospital licensed in accordance with Chapter 23-17 of the Rhode Island General Laws, as amended, is required to restock supplies listed by the Director of Health that are used by a licensed emergency medical services provider in transporting emergency patients to such hospital.

24.21.1 Restocking will not be required: (i) in the absence of documentation of supply usage on the emergency patient's R.I. EMS ambulance run report or (ii) if the licensed emergency medical services provider bills any third party payer for the supplies which were used.

24.21.2 The listing of supplies that are subject to mandatory restocking in accordance with section 24.21 (above) is available by contacting:

Rhode Island Department of Health, Office of Emergency Medical Services
3 Capitol Hill, Room 105
Providence, RI 02908
401-222-2401

Diversion Plan -- Disaster Planning and Response

24.22 Hospitals with an emergency department or service shall maintain participation in and compliance with the *Rhode Island Diversion Plan* of reference 76 herein. Such compliance shall include retaining all required communication devices (e.g., Nextel system) in good operating condition and training of an adequate number of staff in the use of communication equipment as it relates to disaster planning/response and the proper execution of the Diversion Plan.

Section 25.0 ***Home Care Services***

25.1 Hospitals with home care services as defined in section 1.23 1.26 herein, shall have an organizational structure designed in accordance with the provisions of section 12.0 (Organization) herein.

25.2 A qualified person shall be responsible for the administrative and coordinating functions of the home care program. Such a person may be the physician responsible for the general direction of the medical services of the program.

25.3 A multidisciplinary group with representatives of the services provided shall be established to serve in an advisory capacity. The group shall meet as frequently as necessary, maintain written documented reports of its proceedings, and shall be responsible for no less than the following:

a) develop and recommend policies as required under sections 18.0 and 19.0 herein, and

such other policies as may be required pertaining to professional and ancillary services provided by and through the program;

b) assist in maintaining liaison with other health care providers;

c) assist in quality improvement program;

d) review annually all program policies and make recommendations; and

e) such other related functions as may be deemed advisable within the scope of responsibility of said group.

25.4 The general responsibility for the medical services provided in connection with the home care program shall be vested in an appropriately designated member of the medical staff in accordance with hospital policy.

25.4.1 Regularly scheduled meetings of personnel responsible for the provision of services (such as program staff, hospital personnel and representatives of participating community agencies) shall be held to affect coordination of patient care services.

25.5 Home health care program personnel shall be qualified to perform their respective duties in accordance with state licensure and acceptable professional qualification standards.

25.6 A policy and procedure manual shall be established which shall contain guidelines specifically related to the program such as:

a) definition of the scope of services offered;

b) admission and discharge policies;

c) procedures to be performed in the home;

d) circumstances that may require the patient to return to the hospital for treatment;

e) care of patients in an emergency; and

f) other such related policies and procedures.

25.7 A medical record shall be maintained for every patient receiving services in accordance with the provisions of section 27.0 herein.

25.8 Arrangements for the provision of services by a participating community agency or individual provider shall be documented by means of a written signed agreement or contract which shall include specific terms governing the mutual responsibilities for the nature, scope and cost of service to be provided.

Section 26.0 ***Laboratory Service***

26.1 The director of laboratory service shall be a member of the medical staff, preferably a pathologist certified by the American Board of Pathology.

26.2 Staff personnel shall be sufficient in number and adequately qualified and licensed, as applicable, pursuant to Chapter 23-16.3 of the Rhode Island General Laws, as amended.

26.3 Laboratories shall have adequate space, equipment and supplies to perform the required volume of work with accuracy, efficiency and shall conform with the fire safety requirements of reference 7.

26.4 Provisions shall be made to assure continuous availability of emergency laboratory services, including blood transfusion services.

Clinical Laboratory Services

26.5 Examination in the fields of hematology, chemistry, microbiology, immunology, urinalysis, immunohematology and other services necessary to meet patient care needs shall be provided within the institution in accordance with standard medical practice and the rules and regulations herein.

26.6 Hospital clinical laboratory services shall be provided in accordance with sections 10.1, 10.2, 10.3, 10.4, 10.5, 12.1, 12.2, 13.1, 13.2, 14.1, 14.2, 14.3, 15.1, 15.2, and 15.2.1 of the regulations of reference 58 herein.

26.7 ***Other Services*:**

26.7.1 Other services not specifically required by these regulations to be provided on-site may be provided either by the hospital directly or by contractual arrangement with a Rhode Island licensed laboratory. Such services may include tissue pathology, cytotechnology, cytogenetics, etc.

26.7.2 In the latter instance, written policies and procedures shall be established governing prompt transportation of specimens and submission of reports; and all surgically removed tissues shall be examined by a pathologist and signed reports shall be included in the patient's medical record.

26.7.3 There shall be a written mechanism for internal and/or external professional review of tissue pathology services as needed.

26.8 ***Autopsy Service*:**

26.8.1 An autopsy service shall be provided either directly by the hospital or by contractual arrangement with another licensed institution.

26.8.2 In either case, the facility shall have adequate space, equipment and personnel for the expected workload; autopsies on reportable death cases shall be subject to the requirements of reference 30.

26.9 ***Blood Banks & Transfusion Services*:**

26.9.1 Each hospital shall provide appropriate facilities and equipment for the procurement, storage and administration of whole blood and blood products either directly or through participation in a multi-facility community blood collection, testing, storage

and processing system. Psychiatric hospitals not providing this service shall be exempt from this requirement.

26.9.2 Written policies and procedures for all phases of operation of blood banks and transfusion services shall be established and periodically revised to comply with standards of reference 8.

26.10 ***Reports*:** Authenticated and dated reports of all pathological and clinical laboratory examinations including autopsies shall be made part of the patient's medical record in a timely manner as determined by hospital policy.

Section 27.0 ***Medical Records***

27.1 The medical record service shall be under the full-time direction of a registered medical record administrator or a registered health information administrator (RHIA) who is certified by the American Health Information Management Association or who possesses equivalent training and experience.

27.2 The medical record department shall be adequately staffed and equipped to facilitate the accurate processing, checking, indexing, filing and retrieval of all medical records.

27.3 A medical record shall be established and maintained for every person treated on an inpatient, outpatient (ambulatory) or emergency basis, in any unit of the hospital. The record shall be available to all other units.

27.4 Written policies and procedures shall be established regarding content and completion of medical records by an appropriate multidisciplinary group. Also, this group shall be responsible for ongoing review.

27.5 Entries in the medical record shall be made by the responsible person in accordance with hospital policies and procedures.

27.6 The medical record shall contain sufficient information to identify the patient and the problem, to describe the treatment and document the results.

27.7 The content of all medical records (inpatient, outpatient, ambulatory and emergency) shall conform with applicable standards of reference 9. Further, medical records shall document the primary language of the patient; shall document any hospital provision of interpretive services by bilingual clinicians, qualified interpreters, or qualified sign language interpreters; and shall document the inability to provide interpretive services by bilingual clinicians, qualified interpreters, or qualified sign language interpreters as required by the patient.

27.8 The medical record, including the discharge summary, shall be completed within thirty (30) days of the patient's discharge.

27.9 Provisions shall be made for the safe storage of medical records in accordance with reference 10.

27.10 All medical records either original or accurate reproductions shall be preserved for a minimum of five (5) years following discharge of the patient in accordance with section 23-3-26 of reference 11.

27.10.1 Records of minors shall be kept for at least five (5) years after such minor shall have reached the age of 18 years.

27.11 A mechanism shall be established to ensure confidentiality of all medical records, including computerized or electronic records.

Patient Access to Medical Records

27.12 Medical records, even though the property of the facility, may be requested by the patient or an authorized representative. All medical record requests shall be made in writing.

27.13 Charges shall not be made if the record is requested for continuity of care purposes or for immunization records required for school admission or by the applicant or beneficiary or individual representing an applicant or beneficiary for the purposes of supporting a claim or appeal under the provision of the Social Security Act or any federal or state needs-based benefit program such as Medical Assistance, RIte Care, Temporary Disability Insurance and Unemployment Compensation.

27.14 No fees shall be charged to applicants for benefits in connection with a Civil Court Certification Proceeding or a claim under the Worker's Compensation Act R.I.G.L. 28-29-38 as reflected in R.I.G.L. 23-17-19.1(16).

27.15 Records must be provided within thirty (30) days of the request or within thirty (30) days of completion of the medical record (whichever is later).

Hospital Closure/ Change in Ownership and Medical Records

27.16 A hospital that voluntarily closes or changes ownership shall initiate a multimedia press release, within thirty (30) days, notifying the public of the facility closure. Such notice shall include the procedure by which individuals may obtain their medical records. In addition, written notification of facility closure and a plan for disposition of medical records shall be provided to the Department at least thirty (30) days prior to the closure/change of ownership of the hospital.

27.17 If a hospital changes ownership, all medical records in original, electronic, or microfilm form shall remain in the hospital or related institution, become part of the ownership agreement, and it shall be the responsibility of the new owner to protect and maintain these records.

27.18 If any hospital shall be finally closed, its medical records may be delivered to any other hospital(s) in the vicinity willing to accept and retain same, or may be delivered to any other lawfully permitted agency.

27.19 Medical records not claimed that are beyond five (5) years of the last date of discharge may be destroyed, provided that the requirements of section 27.10.1 (above) are met. Patients or their representatives shall be provided with an opportunity to claim their records prior to destruction of the records in the event of closure or change in ownership of the hospital .

Section 28.0 ***Nursing Service***

28.1 Each hospital shall have an organized nursing department. A registered nurse qualified on the basis of education, experience and clinical ability shall be responsible for the nursing service.

28.2 There shall be a sufficient number of registered nurses on duty at all times to plan, assign, supervise and evaluate nursing care as well as to provide direct patient care as required.

28.2.1 There shall be a registered nurse on each inpatient unit at all times.

28.3 The number and type of registered nurses and ancillary nursing personnel shall be based on evaluation of patient care needs and staff capabilities for each patient care unit.

28.3.1 The hospital shall designate a registered nurse responsible for development of a written nursing staffing plan. This plan shall be:

a) specific by nursing unit;

b) developed in collaboration with nursing representation from each unit; and

c) flexible to respond to changes in patient acuity and/or census.

28.4 Nursing personnel shall be assigned to patient care units in a manner that minimizes the risk of cross-infection and accidental contamination.

28.5 There shall be written evidence that the nursing service provides safe and effective nursing care, through the comprehensive assessment and planning of each patient's care based upon such assessment and the implementation of the plan.

Section 29.0 ***Nuclear Medicine***

29.1 Hospitals with nuclear medicine service may provide such services either directly or per contractual arrangement with another facility having a licensed program in accordance with reference 14.

29.2 The direction of the nuclear service shall be provided by a member of the medical staff who through education and experience is qualified in nuclear medicine.

29.3 Policies and procedures shall be adopted for the receiving, handling, use, storage and disposition of radioactive isotopes based on the guidelines of reference 32.

29.4 The type, quantity and quality of equipment for the nuclear medicine service shall be adequate to conduct reliable diagnostic studies and treatment.

29.5 There shall be quality control procedures and a quality management program as required under Part "C" of the *Rules and Regulations for the Control of Radiation* (*R23-1.3-RAD*) of reference 14.

29.6 Records of services rendered shall be maintained and incorporated in the patient's medical record. Other records as required by law shall be maintained.

Radiobioassay Examinations

29.7 A nuclear medicine department performing radiobioassay examinations shall comply with the *Rules and Regulations for the Control of Radiation*, promulgated by the Rhode Island Department of Health, Office of Occupational and Radiological Health. Furthermore, the nuclear medicine department shall be registered with the Office of Occupational and Radiological Health and conform to such directives as may be promulgated by the Department of Health for possession and use of radioactive materials.

Section 30.0 ***Outpatient (Ambulatory Care) Services***

30.1 All hospital outpatient (ambulatory care) services shall conform to all applicable rules and regulations herein, since such services are an integral part of the hospital and covered under its license.

Section 31.0 ***Pharmaceutical Service***

31.1 Each hospital shall provide pharmaceutical services either directly within the institution or by contractual arrangement. In either instance, there shall be evidence of a current pharmacy license in compliance with section 5-19-28 of reference 13. Pharmaceutical services shall be provided in accordance with the regulations of reference 62 herein.

Section 32.0 ***Medical Imaging Services***

32.1 Each hospital, except those psychiatric hospitals who elect not to provide medical imaging services, shall maintain such services including provisions for emergency coverage, directed by a qualified radiologist, preferably one certified by the American Board of Radiology or having the equivalent in training and experience.

32.2 Hospitals maintaining radiotherapy services shall provide for their safe and effective operation under a director qualified by training and experience in therapeutic radiology.

32.3 X-ray equipment facilities and services shall be registered with the Office of Occupational and Radiological Health in accordance with Part B of reference 14.

32.4 Sufficient technical personnel shall be available, consistent with the scope of services provided.

32.5 Adequate space and equipment shall be provided for medical imaging services including facilities for processing and storage of films and records.

32.6 Authenticated reports of the radiologist's interpretation, consultation and therapy shall be part of the patient's medical record.

32.7 Reports and films shall be preserved in accordance with section 27.9 herein.

32.8 All aspects of mammography services shall be managed in accordance with the provisions of the *Rules & Regulations Related to Quality Assurance Standards for Mammography (R23-1-MAM*) of the Rhode Island Department of Health and the applicable U.S. Food and Drug Administration (USFDA) regulations in 21 CFR, pursuant to the Mammography Quality Standards Act of 1992.

Section 33.0 ***Radiation Safety***

33.1 The requirements of Parts "A" and "F" of reference 14 pertaining to x-ray equipment, safety precautions, monitoring of personnel and areas, administrative procedures, maintenance of records and other requirements shall apply to medical imaging services.

33.2 The requirements of Part "H" of reference 14 pertaining to particle accelerators shall apply to radiotherapy services utilizing particle accelerators.

Section 34.0 ***Reporting of Hospital Events & Incidents***

Reportable Deaths:

34.1 All patient deaths occurring within the hospital, which are reportable in accordance with reference 30, shall be reported to the Office of State Medical Examiners.

34.2 In addition to the above, hospitals shall be subject to the appropriate requirements of reference 30.

Reportable Events:

34.3 The hospital shall, within 24 hours of receipt of such information, notify the licensing agency of any reportable event as defined in section 1.49 herein on a form and in a manner specified by the Department.

34.4 In cases of kidnapping or elopement, the report to the licensing agency shall include: patient medical record number; date and circumstances of the kidnapping/elopement; and outcome (e.g., return to hospital, adverse effect, etc.) Peer review and follow-up reporting shall be conducted as required in sections 34.10 and 34.11 herein.

34.5 Health care facilities shall provide the licensing agency with prompt notice of pending and actual labor disputes/actions which would impact delivery of patient care services including, but not limited to, strikes, walk-outs, and strike notices. Health care facilities shall provide a plan, acceptable to the Director, for continued operation of the facility, suspension of operations, or closure in the event of such actual or potential labor dispute/action.

Reportable Incidents:

34.6 The hospital shall ensure that any employee who has reasonable cause to believe a reportable incident, as defined in section 1.50 herein, has occurred reports such information to a high managerial agent within twenty-four (24) hours of receipt of such information on a form and in a manner specified by the Department.

34.7 The hospital must maintain records of such reports including all subsequent actions taken.

34.8 Any reportable incident occurring on or after June 30, 1994 shall be reported in writing to the Department of Health within seventy-two (72) hours of when the hospital has reasonable cause to believe an incident has occurred. Any incident(s) occurring prior to June 30, 1994 need not be reported.

34.9 Written report shall be in compliance with section 62.0 63.0 herein and shall include a patient medical record number but no personal identifier.

34.10 The hospital shall ensure an appropriate committee or multidisciplinary group conducts peer review for all reportable incidents. The hospital shall notify the licensing agency of the outcome of the internal review as soon as this information is available but in no case later than six (6) months after the initial report and if the findings determine that the incident was within the normal range of outcomes, no further action shall be required.

34.11 If findings conclude that the incident was not within said normal range, the hospital shall conduct a root cause analysis or other appropriate process for incident investigation to identify causal factors that may have led to the incident and shall develop a performance improvement plan to prevent similar incidents from occurring in the future. The hospital shall provide the licensing agency the following information:

a) an explanation of the circumstances surrounding the incident;

b) an updated assessment of the effect of the incident on the patient;

c) a summary of current patient status including follow-up care and post incident diagnosis;

d) a summary of all actions taken to correct identified problems to prevent recurrence of the incident and/or improve overall patient care; and

e) a copy of the performance improvement plan developed as a result of the incident investigation.

Other Reporting Requirements:

34.12 The hospital shall forward to the licensing agency copies of all hospital notifications and reports made in compliance with the federal Safe Medical Devices Act of 1990.

34.13 The hospital shall report within 24 hours, to the licensing agency, allegations of patient abuse, neglect or mistreatment as defined in Chapter 23-17.8 of the Rhode Island General Laws, as amended.

Section 35.0 ***Social Services***

35.1 Every hospital shall provide social services within the scope of a defined plan.

35.2 A social worker qualified on the basis of education, training and experience in accordance with the provisions of Chapter 5-39.1 of the Rhode Island General Laws, as amended, shall supervise the delivery of social services on a full, part-time, or consultative basis.

35.3 The service shall be staffed by a sufficient number of social workers, qualified on the basis of education, training and experience in accordance with the provisions of Chapter 5-39.1 of the Rhode Island General Laws, as amended.

35.4 Appropriate records shall be maintained and included in the patient's medical record.

Section 36.0 ***Surgical Service***

36.1 Hospitals in which surgery is performed shall maintain an operating suite and a surgical department/service.

36.2 The surgical department/service shall be governed under rules and regulations which include surgical staff privileges, supporting services of other professional and paramedical personnel, provisions for emergency coverage and operating suite procedures, including standards of reference 28.

36.3 The operating suite shall be:

a) under the supervision of a person qualified by training and experience in operating room service;

b) adequately designed, to include operating and recovery rooms, proper scrubbing, sterilization and dressing room facilities, storage for anesthetic agents and shall be adequately equipped as required by the scope and complexity of services;

c) in compliance with safety requirements of reference 16, and all other codes and regulations of section 53.1 54.1 herein; and

d) provided with prominently posted policies and procedures pertaining to safety controls.

36.4 A roster of current surgical privileges of every surgical staff member shall be maintained on file in the operating suite.

36.5 An operating room register shall be maintained which shall include as a minimum: patient's name, hospital number; pre and post-operative diagnosis; complications, if any; name of surgeon; first assistant, anesthetist, scrub and circulating nurse; operation performed; and type of anesthesia.

36.6 The medical staff shall develop a policy acceptable to the Director identifying which tissue/specimens removed at surgery shall be submitted for pathological examination.

36.7 Policies and procedures governing infection control and reporting techniques shall be established in accordance with section 51.1 (d) herein.

36.8 The patient's medical record shall be available in the surgical suite at time of surgery and shall contain no less than the following information which shall be documented prior to surgery:

a) a medical history, physical examination and laboratory studies in accordance with section 19.3 herein;

b) a signed consent for surgical procedure except in emergencies; and

c) a pre-operative diagnosis.

36.9 An accurate and complete description of operative procedure including post-operative diagnosis shall be recorded by the operating surgeon within 48 hours following completion of surgery.

Section 37.0 ***Anesthesia Service***

37.1 In hospitals with an anesthesia department/service, said department/service shall be under the direction of a board-certified anesthesiologist and shall be organized under written policies and procedures regarding staff privileges, emergency coverage on a twenty-four (24) hour basis, the administration of anesthetics, the maintenance of safety controls and qualifications and supervision of non-physician anesthetists and trainees.

37.2 Policies shall include provisions, in addition to the above, for the following:

a) pre-anesthesia evaluation by a physician;

b) safety of the patient during the anesthesia period;

c) review of patient's condition prior to induction of anesthesia and post anesthetic evaluation;

d) recording of all events related to each phase of anesthesia care, including the development of an intraoperative anesthesia record; and

e) the administration of anesthetics, including conscious sedation, in any setting in the hospital.

37.3 With respect to *inpatients*, a post-anesthesia evaluation shall be documented within forty-eight (48) hours after surgery by the individual who administered the anesthesia. If the person who administered the anesthesia is on leave (e.g., holiday, vacation, sick), an exception to this requirement shall be permitted.

37.4 With respect to *outpatients*, a post-anesthesia evaluation to assess proper anesthesia recovery shall be performed prior to discharge. All post-anesthesia evaluations shall be performed by the individual who administered the anesthesia or another qualified anesthesia provider.

37.5 Anesthesia shall only be administered by:

a) a qualified anesthesiologist;

b) a doctor of medicine or osteopathy (other than an anesthesiologist);

c) a dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law or regulation;

d) a certified registered nurse anesthetist (CRNA) acting within his/her scope of practice and as authorized by the governing body;

e) a physician assistant acting within his/her scope of practice and as authorized by the governing body;

f) a certified nurse-midwife acting within his/her scope of practice and as authorized by the governing body;

g) a certified registered nurse practitioner acting within his/her scope of practice and as authorized by the governing body.

Section 38.0 ***Obstetric Service***

38.1 Hospitals with an obstetric service shall provide adequate and comprehensive care to mothers and their newborn infants in an environment which provides protection from infection and cross-infection.

38.2 Written policies and procedures shall be developed to cover alternative use of obstetrical beds. These may include, but need not be restricted to patients undergoing "clean" gynecologic surgery.

38.3 The obstetric unit shall be under the general supervision of a registered nurse with training and experience in obstetric nursing.

38.4 The practice of midwifery shall be governed by the statutory and regulatory provisions of reference 35; all policies, procedures and protocols shall be approved by the medical staff and the governing body.

38.5 Hospitals with an obstetric service shall have no less than the following supportive services available on a twenty-four (24) hour basis:

a) diagnostic x-ray;

b) blood or blood component transfusion service;

c) clinical laboratory; and

d) anesthesia service in accordance with section 37.0 herein.

38.6 Satisfactory provisions shall be made for the care of patients in labor in adequately equipped labor rooms, conveniently located to the delivery room.

38.7 The delivery room(s) shall be of sufficient number and size to accommodate expected case load, personnel and equipment.

38.8 The delivery room shall meet applicable codes and regulations of sections 54.0 and 55.0 herein.

38.9 Hospitals performing both surgery and obstetric services shall maintain individually identified surgical and obstetric suites. Shared overflow facilities may be considered under special circumstances with advance approval of the licensing agency.

38.10 Provisions shall be made within the delivery area for the immediate care of emergencies with all necessary emergency equipment available.

38.11 An acceptable method and procedure shall be established for the positive associative identification of mother and child in the delivery room.

38.12 Facilities shall be available and policies and procedures established for maternity patients requiring isolation in accordance with section 51.0 herein.

38.13 A medical record shall be maintained for each mother and newborn and the applicable standards of references 19 and 20 shall serve as guidelines in determining minimum content.

38.13.1 A record of any prenatal care rendered shall be on file at the hospital and become part of the patient's medical record.

38.14 Where not otherwise covered in these regulations, the standards of reference 20 shall serve as a guide in defining adequacy of the practices, facilities and equipment in the obstetric unit.

38.15 A policy and procedure manual shall be established which contains guidelines specifically related to the administration and management of clinical services pertaining to no less than the following:

a) definition of the limits of practice and services provided;

b) a signed informed consent which attests to the patient's full awareness of the type of services provided, and the hospital's recognition of parental choice for specific care

services, except in emergency situations and provisions required by law;

c) the orientation and childbirth education program for expectant mothers;

d) plan of care to be developed by staff with the participation of the patient; such plan shall be mutually acceptable to the patient and staff but must include those provisions required by law. Furthermore, the plan shall identify parental choices pertaining to such services as the use of anesthesia; breast-feeding; circumcision of newborn male; and need for postpartum supportive services;

e) medical consultation (pediatric, OB/GYN or other);

f) the use of controlled substances;

g) accessibility to diagnostic services including laboratory, sonography, medical imaging, electronic monitoring, intensive care;

h) permitting the attendance of partners and/or family members during labor and delivery;

i) postpartum care based on acceptable standards for follow-up and evaluation after discharge which includes no less than:

I. provisions for the immediate postpartum care and assessment of newborn; eye prophylaxis to newborn; Rhogam test; metabolic screening and other tests for the newborn as may be required by law; postpartum examination; assessment of mother-child relationship including breast-feeding; follow-up care and family planning; preparation and submission of birth certificates; instruction in child care; immunizations and such other intrapartum and postpartum care as may be appropriate; and

j) such other as may be deemed necessary and appropriate.

38.16 Mothers may be discharged only if prenatal, perinatal and infant risk factors have been identified and documented according to the perinatal screening protocol of the Department (see Appendix "A") and the discharge plan includes confirmed arrangements for appropriate home and community follow-up services to address those risks. (See also sections 39.7; 39.8; 39.10 and 38.14 herein).

Section 39.0 ***Newborn Service***

39.1 Hospitals with a newborn service shall have a registered nurse with experience in the care of the newborn and shall be responsible for the nursing care of newborn infants. The appropriate nursing personnel shall be present in the nursery at all times.

39.2 Access to the nursery shall be limited to parents and personnel who are immediately concerned with the care of the newborn and the nursery environment and who are free of communicable infections.

39.3 The nursery shall be located and arranged to provide complete protection of newborn infants from infection and cross-infection and nursery accommodations shall include but shall not be limited to:

39.3.1 A regular nursery for the care of healthy infants, excluding:

a) infants with transmissible disease;

b) infants born to a mother who is a carrier or is infected by transmissible disease;

c) infants born outside the hospital or readmitted with suspected transmissible disease;

d) infants who are exposed to or have been infected; and

e) other infants excluded by the medical staff.

39.3.2 An isolation facility for the care of newborn infants with a suspected or confirmed diagnosis of infection.

39.3.3 A premature nursery for the care of premature infants or other high risk and seriously ill infants with non-infectious conditions. Vigorous healthy premature infants may be cared for in their own protected environment, such as in a standard incubator in the regular nursery.

39.4 A defined policy for the care of infants born outside the hospital, for infants born of a mother who has had no prenatal care, or for infants suspected of harboring an infectious disease.

39.5 The ventilation system shall maintain positive pressure in the nursery and shall be installed in accordance with section 7.31 of reference 17.

39.6 Prophylactic treatment to the eyes of newborn infants shall be administered in accordance with section 23-13-12 of reference 18.

39.7 The physician attending a newborn child shall cause said child to be subject to the tests listed in the *Rules and Regulations Pertaining to the Fee Structure for the Newborn Metabolic and Sickle Cell Disease Control Program and the Newborn Hearing Impairment Screening Program (R23-13-MET/HRG)* of reference 47.

39.8 An adequate record of the pertinent facts of the gestation and immediate neonatal period shall accompany the infant to the nursery and become part of the infant's medical record and may be used to assist in conducting risk assessments for discharge planning and public health services.

39.9 Where otherwise not covered in these regulations, the standards of reference 19 shall serve as a guide in defining the adequacy of facilities, equipment, furnishings and practices in the newborn nursery and formula room.

39.10 Hospital staff shall develop a multidisciplinary discharge plan for any drug exposed baby, pursuant to section 24 of Chapter 42-72-5 of the Rhode Island General Laws, as amended.

39.11 Infants may be discharged only if prenatal, perinatal and infant risk factors have been identified and documented according to the perinatal screening protocol of the Department

(see Appendix "A") and the discharge plan includes confirmed arrangements for appropriate home and community follow-up services to address those risks. (See also sections 39.7; 39.8; 39.10 and 38.14 herein).

39.12 Each hospital that provides newborn/obstetrical services shall report to the Department the following data for each fiscal year:

a) the number of births;

b) the number of very low birth weight neonates (501--1500 grams);

c) the number of low birth weight neonates (1501 -- 2500 grams);

d) neonatal mortality rates by birth weight class;

e) admissions and transfers to neonatal intensive care units.

39.13 Each hospital that provides newborn/obstetrical services shall maintain records of morbidity rates of neonates for nosocomial infections, necrotizing enterocolitis, bronchopulmonary dysplasia, and intraventricular hemorrhage.

39.14 Each hospital that provides newborn/obstetrical services shall report annually to the Department its survival rates for the hospital fiscal year as compared with the most recent rates reported by the National Institute of Child Health and Human Development Neonatal Network and the morbidity rates specified in section 39.13 (above). If the survival rate for the hospital's newborn unit is lower than the survival rates reported by the National Institute of Child Health and Human Development Neonatal Network by more than twenty-five percent (25%), the newborn unit shall file a written plan with the Department for the identification of the cause(s) of excess mortality and a plan for correction, if indicated.

Section 40.0 ***Birth Center Service***

40.1 Hospitals with an obstetric service may elect to have a birth center service as defined in section 1.4 herein. An organizational structure for such service shall be designed in accordance with section 12.0 herein.

40.2 The birth center service shall be under the direction of a medical director who is a board certified obstetrician/gynecologist, with full obstetrical privileges, and who shall be responsible for all the clinical and medical matters pertaining to the management of pregnancy, birth, postpartum, newborn and gynecological health care of low-risk women, including the approval of written policies and procedures and protocols for midwifery care management where appropriate and applicable.

40.2.1 "Low-Risk" refers to expected normal, uncomplicated prenatal course, assisted by adequate prenatal care and prospects for a normal uncomplicated birth based on continual screening for high risk factors which would preclude admission to the center, or require referral and/or transfer from the center in accordance with the transfer policies pursuant to section 18.1 (f) herein.

40.3 A midwife licensed in this state or a physician with obstetric privileges may be designated to direct the administrative operation of the center and the management of clinical services.

40.4 An appropriate number of qualified professionals and ancillary personnel shall be assigned to the birth center service. Two (2) staff members shall be in attendance at each birth, one of the two shall be a physician with hospital obstetric privileges or a midwife with delivery privileges and licensed in this state. The other member may be a licensed midwife with delivery privileges, an obstetric physician, or licensed physician assistant with training and experience in obstetric care and resuscitation of the newborn, or a licensed nurse with training and experience in obstetric care and resuscitation of the newborn.

40.4.1 The practice of midwifery shall be governed by the statutory and regulatory provisions of reference 35; all policies, procedures and protocols shall be approved by the medical director and the governing body.

40.4.2 There shall be on the premises at all times, when a woman is in labor, a staff person who holds a current certificate in cardiopulmonary resuscitation from a recognized program such as the American Heart Association.

40.4.3 Whenever one or more women in labor are on the premises, there shall be one staff member in excess to the number of women in labor.

40.5 A policy and procedure manual shall be established which contains guidelines specifically related to the administration and management of clinical services pertaining to no less than the following:

a) definition of the limits of practice and services provided;

b) the criteria for the selection of clients based on established medical and social risk factors associated with possible poor outcomes and utilizing as guidelines no less than the risk factors of reference 36, which would preclude admission to the center;

c) the criteria for the referral and/or transfer of clients and/or newborn utilizing as guidelines the high risk factors of reference 36;

d) a signed informed consent which attests to the client's full awareness of the type of services provided at the birth center, and the birth center's recognition of parental choice for specific care services, except in emergency situations and provisions required by law;

e) the orientation and childbirth education program for expectant mothers, based on the provisions of reference 36;

f) plan of care to be developed by staff with the participation of the client; such plan shall be mutually acceptable to the client and staff but must include those provisions required by law. Furthermore, the plan shall identify parental choices pertaining to such services as the use of anesthesia in accordance with reference 36; breast-feeding, circumcision of newborn male, and need for postpartum supportive services. Such plan shall be based on the provisions of reference 36;

g) prenatal care to be provided either directly at the birth center or in another setting as

approved by the medical director and the governing body; and provided, the professional staff providing the prenatal care meets the staff requirements herein, and policies are established by the medical director governing the prenatal care practices and admission criteria of a woman in active labor, which are consistent with the birth center services practice;

h) medical consultation (pediatric, OB/GYN or other);

i) the use of controlled substance;

j) the use of anesthesia in accordance with reference 36;

k) accessibility to diagnostic services including laboratory, sonography, medical imaging, electronic monitoring, intensive care;

l) labor and delivery (including provisions pertaining to section 5.1.1 herein);

m) permitting the attendance of partners and/or family members during labor and delivery;

n) the provision of services on a twenty-four (24) hour basis;

o) postpartum care based on acceptable standards for follow-up programs of care and postpartum evaluation after discharge which includes no less than:

   i. discharge of mother and newborn generally within twenty-four (24) hours after birth;

   ii. accessibility by telephone, twenty-four (24) hours a day of center's physician, midwife or nurse to assist mothers in case of need during postpartum period;

   iii. home visitation within twenty-four (24) hours of discharge by a member of the center's professional staff to insure continuity of care and assessment of mother and newborn;

   iv. provisions for the immediate postpartum care and assessment of newborn; eye prophylaxis to newborn; Rhogam test; metabolic screening and other tests for the newborn as may be required by law; postpartum examination; assessment of mother-child relationship including breast-feeding; follow-up care and family planning; preparation and submission of birth certificates; instruction in child care; immunizations and such other intrapartum and postpartum care as may be appropriate; and

p) such other as may be deemed necessary and appropriate.

40.6 A mechanism shall be established for the systematic review of professional and administrative services and the quality improvement program.

40.7 A clinical record shall be maintained for every client and newborn in accordance with the appropriate provisions of section 27.0 herein.

40.8 ***Food Services*:** provisions shall be made for the availability of appropriate nourishments and light snacks for clients and family members.

40.9 ***Physical Setting and Equipment*:** birth center service shall be provided in a home-like environment, designated and equipped to protect the health and safety of clients and personnel, and to facilitate emergency exit for the transfer of mothers and/or newborns in the event of emergency.

40.9.1 Reception areas, examination room, family rooms and other supportive areas shall be provided and designed to give privacy and comfort to clients and their families.

40.9.2 The birth room shall be spacious enough to accommodate staff to move freely and to include at least:

a) a large bed or double bed;

b) chairs (lounge and straight-back);

c) a bassinet;

d) space for birth room supplies and equipment and family belongings; and

e) access to a sink with hot and cold running water with elbow-wrist controls.

40.9.3 Acceptable toilet facilities shall be available to each laboring woman and adequate shower facilities shall also be available.

40.9.4 Provisions shall be made for areas such as medication and storage areas, utility areas and such others as may be necessary.

40.9.5 Equipment in the birth center shall be limited to those items needed to provide low risk maternity care and shall include equipment to initiate emergency procedures in life threatening events to mothers and newborns. Such equipment shall include:

a) oxygen and positive pressure masks;

b) delee trap suction and infant laryngoscope and airways;

c) IV equipment;

d) blood expanders;

e) medications identified in protocols for emergency needs; and

f) infant transport equipment and infant warmers.

40.10 Mothers and infants may be discharged only if prenatal, perinatal and infant risk factors have been identified and documented according to the perinatal screening protocol of the Department (see Appendix "A") and the discharge plan includes confirmed arrangements for appropriate home and community follow-up services to address those risks. (See also sections 39.7; 39.8; 39.10 and 38.14 herein).

Section 41.0 ***Tertiary Care Services: Neonatal Intensive Care Units (NICUs)***

Approval to Operate a NICU and General Requirements

41.1 In order to use the designation "*neonatal intensive care unit*" or "*NICU*", a hospital shall obtain approval from the Department's Office of Facilities Regulation. Said approval shall be issued by the Department if the NICU meets the requirements defined herein.

a) Each hospital shall renew this NICU designation annually.

41.2 Upon satisfactory review of all requested documentation and upon the determination that the hospital has achieved the volume/quality standards described herein, the Department shall approve the hospital's designation as a NICU.

41.3 A hospital that has not received approval by the Department under this section shall not use the designation "neonatal intensive care unit" or "NICU" or any substantially similar phrase to describe any such services provided and shall not provide neonatal intensive care unit services.

41.4 A hospital that operates a neonatal intensive care unit approved by the Department shall maintain capabilities and provide services that include, but are not limited to, those capabilities and services described in sections 41.14, 41.15 and 41.16 (below). A hospital that operates a neonatal intensive care unit approved by the Department shall upgrade its capabilities and services as needed to meet the recommendations of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

41.5 A hospital that operates a NICU and determines that the NICU no longer meets minimum standards herein shall notify the Department of Health and file a plan of correction within fifteen (15) days of such determination by a hospital. The plan of correction shall be subject to section 65.0.

41.6 A NICU shall provide consultation, transportation, and professional educational offerings to staff of other obstetrical facilities in the state.

41.7 A hospital that operates a neonatal intensive care unit approved by the Department shall have written protocols in place that incorporate the following components:

a) continuous involvement of parents in an infant's care to maximize pre-discharge education regarding care of the infant;

b) nursing orientation and ongoing inservice education in the theory and skills necessary to function in a neonatal intensive care unit environment;

c) emergency transport of infants to the neonatal intensive care unit from other facilities;

d) administration, credentialing of staff, and staffing patterns of the neonatal intensive care unit.

Minimum Standards: Volume

41.8 An existing neonatal intensive care unit shall maintain an average daily census of at least fifteen (15) neonates.

41.9 As part of the approval process for a new (or proposed) neonatal intensive care unit, the hospital shall provide data to the Department demonstrating a reasonable expectation of referrals of high risk maternity patients so that an average daily census of at least fifteen (15) neonates is achievable within two (2) years of its opening date.

41.10 As part of the approval process for a new (or proposed) neonatal intensive care unit, the hospital shall also provide any available data to the Department regarding whether the addition of the proposed neonatal intensive care unit is likely to result in the average daily census falling below fifteen (15) neonates at any existing neonatal intensive care unit(s) in the state. If this outcome is likely, the proposal shall describe how the overall quality of care for all very low birth weight neonates in the state will be improved with the addition of the proposed unit.

Minimum Standards: Survival Rates

41.11 Each hospital that has an approved neonatal intensive care unit shall maintain a record of the neonatal survival rate (i.e., the rate at twenty-eight [28] days after delivery) and survival rate at discharge for very low birth weight neonates by 250 gram weight groups (i.e., 501--750 grams, 751--1000 grams, 1001--1250 grams, 1251--1500 grams).

41.12 Each hospital shall maintain records of morbidity rates of neonates for nosocomial infections, necrotizing enterocolitis, bronchopulmonary dysplasia, and intraventricular hemorrhage.

41.13 Each hospital shall report annually to the Department its survival rates for the hospital fiscal year as compared with the most recent rates reported by the National Institute of Child Health and Human Development Neonatal Network and the morbidity rates specified in section 41.12 (above). If the survival rate for the hospital's neonatal intensive care unit is lower than the survival rates reported by the National Institute of Child Health and Human Development Neonatal Network by more than twenty-five percent (25%), the neonatal intensive care unit shall file a written plan with the Department for the identification of the cause(s) of excess mortality and for correction of the rates.

Staffing Requirements

41.14 A hospital that operates a neonatal intensive care unit approved by the Department shall be in compliance with the following staffing requirements:

a) A board-certified neonatologist licensed in Rhode Island shall be designated as the medical director of the neonatal intensive care unit;

b) The registered nurse who has responsibility and accountability for the twenty-four (24) hour nursing management of the neonatal intensive care unit shall, at a minimum, be licensed in Rhode Island, have earned a bachelor's degree in nursing with additional education in neonatology, and have three (3) years of clinical experience, two (2) of which are in the specialty area of neonatology;

c) A registered dietitian licensed in Rhode Island with experience in neonatal nutrition

shall actively participate in the management of neonates in the neonatal intensive care unit;

d) A respiratory therapist licensed in Rhode Island and trained in the neonatology specialty area shall be available to the neonatal intensive care unit twenty-four (24) hours per day.

Service Requirements

41.15 A hospital that operates a neonatal intensive care unit approved by the Department shall provide services that include but are not limited to the following:

a) twenty-four (24) hour emergency transport team for transferring sick newborns from the birth facility to the neonatal intensive care unit;

b) ventilatory assistance and/or complex respiratory management;

c) capability of continuous intravenous administration of vasopressor agents;

d) insertion and maintenance of all types of venous and arterial lines;

e) phototherapy;

f) exchange transfusions;

g) continuous cardiorespiratory monitoring;

h) complex nutritional and metabolic management including total parenteral nutrition;

i) extensive pediatric radiology, diagnostic imaging, and subspecialty services;

j) full range of laboratory services including microchemistry available on a twenty-four (24) hour basis;

k) pharmacy services experienced in neonatal medications and dosage;

l) surgical therapies and post-surgical care for the neonate;

m) access to pediatric subspecialty consultation;

n) availability of developmental consultation;

o) organized interdisciplinary process for continuous quality monitoring;

p) crisis-oriented support and ongoing psychosocial services, including social work services and the availability of psychiatric consultation for the parents of the neonate.

Equipment Requirements

41.16 A hospital that operates a neonatal intensive care unit approved by the Department shall maintain equipment in good working order that includes but is not limited to the following:

a) incubators;

b) cardiorespiratory monitors with high/low alarm and oximeters;

c) warming tables;

d) infusion pumps;

e) oxygen humidification and warming systems;

f) oxygen analyzer;

g) transcutaneous blood gas monitors;

h) arterial and venous catheterization equipment;

i) resuscitation and other life support medications and equipment;

j) ventilators with heated humidity and alarm systems;

k) transducers for invasive cardiac monitoring;

l) transport incubators.

Penalties for Noncompliance

41.17 The penalties for violations of the standards set forth in section 40.0 herein shall be in accordance with those set forth in Chapter 23-17 of the Rhode Island General Laws, as amended and section 7.0 herein. Failure to maintain the minimal neonatal intensive care unit standards set forth herein may result in the revocation or suspension of the hospital's neonatal intensive care unit designation and/or cessation of its activities. A hospital shall post notices for patients and shall notify physicians if its designation as an approved neonatal intensive care unit has been revoked or suspended.

Section 42.0 ***Tertiary Care Services: Primary and/or Elective Percutaneous Coronary Intervention Programs***

Approval to Operate a Primary and/or Elective Percutaneous Coronary Intervention Program and General Requirements

42.1 In order to use the designation "*primary percutaneous coronary intervention program*" and/or "*elective percutaneous coronary intervention program*", a hospital shall obtain approval from the Department's Office of Facilities Regulation. Said approval shall be issued by the Department if the primary and/or elective percutaneous coronary intervention program meets the requirements defined herein.

a) Each hospital shall renew primary and/or elective percutaneous coronary intervention program designation annually.

42.2 Upon satisfactory review of all requested documentation and upon the determination that the hospital has achieved the volume/quality standards described herein, the Department shall approve the hospital's designation as a primary and/or elective percutaneous coronary intervention program.

42.3 A hospital that has not received approval by the Department under this section shall not use the designation "primary percutaneous coronary intervention program", or "elective percutaneous coronary intervention program", or any substantially similar phrase, to describe

any such services provided and shall not perform primary and/or elective percutaneous coronary interventions.

42.4 A hospital that operates a primary and/or elective percutaneous coronary intervention program approved by the Department shall maintain capabilities and provide services that include, but are not limited to, those capabilities and services described in sections 42.11, 42.12 and 42.13 (below). A hospital that operates a primary and/or elective percutaneous coronary intervention program approved by the Department shall maintain its capabilities and services as needed to meet the recommendations of the American College of Cardiology and the American Heart Association.

42.5 A hospital that operates a primary and/or elective percutaneous coronary intervention program and determines that primary and/or elective percutaneous coronary intervention program no longer meets minimum standards herein shall notify the Department of Health and file a plan of correction within fifteen (15) days of such determination by a hospital. The plan of correction shall be subject to the provisions of section 65.0 herein.

42.6 A hospital that operates an approved elective percutaneous coronary intervention program shall have an approved primary percutaneous coronary intervention program available on-site.

Minimum Standards: Volume

42.7 a) An existing primary percutaneous coronary intervention program shall maintain an annual minimum volume of at least thirty six (36) primary percutaneous coronary intervention procedures.

b) An existing elective percutaneous coronary intervention program shall maintain an annual minimum volume of at least two hundred (200) percutaneous coronary intervention procedures.

42.8 a) As part of the approval process for a new (or proposed) primary percutaneous coronary intervention program, the hospital shall provide data to the Department demonstrating a reasonable expectation of attaining and maintaining a minimum volume of thirty six (36) primary percutaneous coronary intervention procedures per year within one (1) year of its opening date.

b) As part of the approval process for a new (or proposed) elective percutaneous coronary intervention program, the hospital shall provide data to the Department demonstrating a reasonable expectation of attaining and maintaining a minimum volume of two hundred (200) elective angioplasty procedures per year within two (2) years of its opening date.

42.9 a) As part of the approval process for a new (or proposed) primary percutaneous coronary intervention program, the hospital shall also provide any available data to the Department regarding whether the addition of the proposed primary coronary angioplasty program is likely to result in the annual volume of procedures performed by existing primary percutaneous coronary intervention programs falling below thirty

six (36) primary percutaneous coronary intervention procedures per year. If this outcome is likely, the proposal shall describe how the overall quality of care for all primary percutaneous coronary intervention patients in the state will be improved with the addition of the proposed program.

b) As part of the approval process for a new (or proposed) elective percutaneous coronary intervention program, the hospital shall also provide any available data to the Department regarding whether the addition of the proposed elective percutaneous coronary intervention program is likely to result in the annual volume of procedures performed by existing elective percutaneous coronary intervention programs falling below two hundred (200) percutaneous coronary intervention procedures per year. If this outcome is likely, the proposal shall describe how the overall quality of care for all elective percutaneous coronary intervention patients in the state will be improved with the addition of the proposed program.

Minimum Standards: Survival Rates and Door-to-Balloon Times

42.10 a) Each hospital that has an approved primary and/or elective percutaneous coronary intervention program shall maintain a record of the inhospital mortality rate and emergency coronary artery bypass graft (CABG) rate (i.e., bypass operation during the same hospital stay) for patients having percutaneous coronary intervention procedures.

b) Each hospital that has an approved primary and/or elective percutaneous coronary intervention program shall participate in a nationally recognized database acceptable to the Director. To the extent possible, risk adjusted rates, based on data from nationally recognized databases and methods acceptable to the Director, shall be used.

c) Each hospital that has an approved primary percutaneous coronary intervention program shall maintain a record of door-to-balloon times for each patient.

42.11 Each hospital shall report the following data to the Department annually: 1.) the emergency coronary artery bypass (CABG) rate for patients having percutaneous coronary intervention; 2.) the hospital's risk-adjusted PCI mortality rate, based on a nationally recognized database and methods acceptable to the Director; 3.) the 95% confidence interval around the hospital's PCI mortality rate; 4.) the national average PCI mortality rate from the national PCI database in which the hospital participates; 5.) the 95% confidence interval around the national PCI mortality rate. If the hospital's annual risk-adjusted PCI mortality rate is statistically significantly higher than the national rate at the 95% level of confidence, then the hospital shall file a corrective action plan.

Staffing Requirements

42.12 A hospital that operates a primary and/or elective percutaneous coronary intervention program approved by the Department shall be in compliance with the following staffing requirements:

a) A board-certified cardiologist licensed in Rhode Island shall be designated as the

director of the cardiac catheterization laboratory that includes the primary and/or elective percutaneous coronary intervention program.

b) Physicians doing primary and/or elective percutaneous coronary intervention procedures shall have training in adult or pediatric interventional cardiology,

c) Each hospital that has an approved primary and/or elective percutaneous coronary intervention program shall have a written procedure for granting and renewing privileges for physician-operators that specifies the required training, experience, board certification, annual volume of procedures, and other factors which will indicate acceptable proficiency.

d) The hospital shall monitor annual procedural volume, complication rates, emergency CABG rates, and inhospital mortality for each operator.

   i) For the purpose of counting procedures, an interventional procedure is defined as a single session with a patient in the procedure room, irrespective of how many or what types of interventions are performed during the session. Only one physician may claim credit for a particular procedure. A physician-operator who claims credit for a procedure is the physician in charge of it. In a teaching program, the trainee will take an active role in the procedure under the direction of the supervising physician, who is responsible. The attending physician who takes primary responsibility for the procedure shall be credited with performing it.

e) The nursing supervisor shall be a registered nurse licensed in Rhode Island familiar with the overall function of the cardiac catheterization laboratory with critical care experience, knowledge of cardiovascular medications, ability to start intravenous solutions, and experience in operating room techniques.

f) At least one (1) technologist, who may or may not be a certified radiological technologist, shall be skilled in radiographic and angiographic imaging principles and techniques.

g) Physicians performing primary percutaneous coronary intervention procedures shall have an annual minimum volume of at least seventy five (75) percutaneous coronary intervention procedures of which at least eleven (11) are primary percutaneous coronary intervention procedures across all hospitals where he/she practices and has privileges.

h) Physicians performing elective percutaneous coronary intervention procedures shall have an annual minimum volume of at least seventy five (75) percutaneous coronary intervention procedures across all hospitals where he/she practices and has privileges.

Service Requirements for Primary and/or Elective Percutaneous Coronary Intervention Programs Without On-Site Coronary Artery Bypass Graft Surgery Program

42.13 a) A hospital that operates an approved primary and/or elective percutaneous coronary intervention program without on-site coronary artery bypass graft surgery program shall establish a memorandum of understanding, acceptable to the Director, with a

hospital that has an on-site coronary artery bypass graft surgery program for transfer of patients requiring emergency cardiac surgery.

b) A hospital that operates an approved primary and/or elective percutaneous coronary intervention program without on-site coronary artery bypass graft surgery program shall develop rapid transfer protocols, acceptable to the Director, with the area emergency medical services provider for transfer of patients requiring emergency cardiac surgery.

Equipment Requirements

42.14 A hospital that operates a primary and/or elective percutaneous coronary intervention program approved by the Department shall have a catheterization laboratory that shall have proper equipment that is appropriate for the types of procedures performed in the laboratory and is in accordance with the guidelines issued periodically by the American College of Cardiology and the American Heart Association.

Quality of Care

42.15 The primary and/or elective percutaneous coronary intervention program shall have regular, frequent, and formal review in a multidisciplinary conference of all deaths and major complications.

42.16 The primary and/or elective percutaneous coronary intervention program shall maintain a database, acceptable to the Director, that collects and analyzes patient data sufficient to analyze utilization and outcome data and to determine the reasons for substantial deviations from the average utilizations and outcomes reported by nationally recognized databases.

Reporting Requirements

42.17 Each hospital with an approved primary and/or elective percutaneous coronary intervention program shall report to the Department for each hospital calendar year:

a) the number of primary and/or elective percutaneous coronary intervention procedures;

b) the number of primary and/or elective percutaneous coronary intervention by primary operator and the number of transfers from another hospital;

c) the number of emergency coronary artery bypass graft surgeries in the same hospital stay following primary and/or elective percutaneous coronary intervention procedures;

d) the number of transfers to another hospital for emergency coronary artery bypass graft surgeries following a primary and/or elective percutaneous coronary intervention;

e) the inhospital mortality rate for primary and/or elective percutaneous coronary intervention patients;

f) the number of primary and/or elective percutaneous coronary intervention procedures

by indication for performing the procedure;

g) the door-to-balloon times for primary percutaneous coronary intervention procedures; and

h) such other data as specified by the Director.

Penalties for Noncompliance

42.18 The penalties for violations of the standards set forth in section 42.0 herein shall be in accordance with those set forth in Chapter 23-17 of the Rhode Island General Laws, as amended, and section 7.0 herein. Failure to maintain the minimal primary and/or elective percutaneous coronary intervention program standards set forth herein may result in the revocation or suspension of the hospital's primary and/or elective percutaneous coronary intervention program designation and/or cessation of its activities. A hospital shall post notices for patients and notify physicians if its designation as an approved primary and/or elective percutaneous coronary intervention program has been revoked or suspended.

Section 43.0 ***Tertiary Care Services: Coronary Artery Bypass Graft Surgical Programs***

Approval to Operate a Coronary Artery Bypass Graft Surgical Program and General Requirements

43.1 In order to use the designation "*coronary artery bypass graft surgical program*", a hospital shall obtain approval from the Department's Office of Facilities Regulation. Said approval shall be issued by the Department if the coronary artery bypass graft surgical program meets the requirements defined herein.

a) Each hospital shall renew this coronary artery bypass graft surgical program designation annually.

43.2 Upon satisfactory review of all requested documentation and upon the determination that the hospital has achieved the volume/quality standards described herein, the Department shall approve the hospital's designation as a coronary artery bypass graft surgical program.

43.3 A hospital that has not received approval by the Department under this section shall not use the designation "coronary artery bypass graft surgical program", or any substantially similar phrase, to describe any such services provided and shall not perform coronary artery bypass graft surgeries.

43.4 A hospital that operates a coronary artery bypass graft surgical program approved by the Department shall maintain capabilities and provide services that include, but are not limited to, those capabilities and services described in sections 43.11, 43.12, 43.13 and 43.14 (below). A hospital that operates a coronary artery bypass graft surgical program approved by the Department shall maintain its capabilities and services as needed to meet the recommendations of the Society of Thoracic Surgery, American College of Cardiology, and the American Heart Association.

43.5 A hospital that operates a coronary artery bypass graft surgical program and determines the that coronary artery bypass graft surgical program no longer meets minimum standards herein shall notify the Department and file a plan of correction within fifteen (15) days of such determination by a hospital. The plan of correction shall be subject to the provisions of section 65.0 herein.

Minimum Standards: Volume

43.6 An existing coronary artery bypass graft surgical program shall maintain an annual minimum volume of at least two hundred and fifty (250) surgical patients who require cardiopulmonary bypass capability, the majority of whom have coronary artery bypass grafts. Patients who have minimally-invasive coronary artery bypass graft operations shall be included in the counted patients.

43.7 As part of the approval process for a new (or proposed) coronary artery bypass graft surgical program, the hospital shall provide data to the Department demonstrating a reasonable expectation, within two (2) years of its opening date, of attaining and maintaining a minimum volume of at least two hundred and fifty (250) surgical patients per year who require the availability of cardiopulmonary bypass.

43.8 As part of the approval process for a new (or proposed) coronary artery bypass graft surgical program, the hospital shall also provide any available data to the Department regarding whether the addition of the proposed coronary artery bypass graft surgical program is likely to result in the annual volume of procedures performed by existing coronary artery bypass graft surgical programs falling below two hundred and fifty (250) procedures per year. If this outcome is likely, the proposal shall describe how the overall quality of care for all coronary artery bypass graft patients in the state will be improved with the addition of the proposed program.

Minimum Standards: Survival Rates

43.9 Each hospital that has an approved coronary artery bypass graft surgical program shall maintain a record of the inhospital mortality rate for patients having coronary artery bypass graft surgery and shall participate in a nationally recognized database acceptable to the Director. To the extent possible, risk adjusted rates, based upon data from nationally recognized databases and methods acceptable to the Director, shall be used.

43.10 Each hospital shall report the following data to the Department annually: 1.) the hospital's risk-adjusted mortality rate for isolated CABG, based on a nationally recognized database and methods acceptable to the Director; 2.) the 95% confidence interval around the hospital's isolated CABG mortality rate; 3.) the national average isolated CABG mortality rate from the national open heart surgery database in which the hospital participates; 4.) the 95% confidence interval around the national isolated CABG mortality rate. If the hospital's annual risk-adjusted isolated CABG mortality rate is statistically significantly higher than the national rate at the 95% level of confidence, then the hospital shall file a plan for identification of the cause of the excess mortality and a plan for correction, in accordance with the requirements set forth in section 64 herein.

Staffing Requirements

43.11 A hospital that operates a coronary artery bypass graft surgical program approved by the Department shall be in compliance with the following staffing requirements:

a) A cardiac surgeon certified by the American Board of Thoracic Surgery or equivalent certifying body shall be designated as director of the coronary artery bypass graft surgical program.

b) A hospital coronary artery bypass graft surgical program should have a minimum of two (2) qualified cardiac surgeons.

c) Each hospital that has an approved coronary artery bypass graft surgical program shall have a written procedure for granting and renewing privileges for surgeons that specifies the required training, experience, board certification, annual volume of open heart procedures, and other factors that will indicate acceptable proficiency. The hospital shall monitor annual procedural volume, complication rates, and inhospital mortality for each surgeon.

d) Other specially trained physicians assisting the cardiac surgeon shall be cardiac surgical assistants, cardiac anesthesiologists, cardiologists, and other qualified consultants.

e) Nursing personnel shall include surgical nurses specially trained in cardiac surgical nursing, cardiac surgery intensive care nursing, and cardiac nurse educators.

f) Perfusionists shall be trained in the preparation, maintenance, and operation of pump-oxygenators and related equipment during open heart surgery and shall be knowledgeable about red blood cell-saving procedures and circulatory assist devices. The perfusionist shall work under the direction of the cardiac surgeon or the cardiac anesthesiologist or both.

g) Other personnel required shall be a full complement of hospital professionals including pharmacists, dietitians, respiratory therapists, social workers and physical therapists with cardiac rehabilitation skills.

Service Requirements

43.12 Coronary angiography of diagnostic quality shall be available. Facilities that treat pediatric patients shall provide for biplane angiography.

Equipment Requirements

43.13 The cardiac operating room shall be a room with requisite space and equipment for open heart surgery. It shall have adequate electrical grounding, oxygen and vacuum supply, proper illumination, and capability of supporting the technical equipment used in cardiopulmonary bypass, including the pump-oxygenators, heat exchange equipment, cell saver, anesthetic apparatus and assist devices.

43.14 The cardiac intensive care units shall be operated under the direction of a qualified physician and have a unit nurse director. It shall have typical intensive care capabilities including continuous electrocardiographic and hemodynamic monitoring and recording and equipment and personnel for full ventilatory support. The space shall accommodate multiple life support systems, such as intraaortic balloon pumps, ventricular and total circulatory assist devices, and hemodialysis machines. Portable chest x-rays should be available twenty-four (24) hours per day. The unit shall be able to obtain immediate reports on blood gas analysis, serum electrolyte measurements, and certain other lab tests. The number of beds shall be one-half (1/2) the number of open heart operations performed each week.

Quality of Care

43.15 The cardiac surgery program shall have regular, frequent, and formal review in a multidisciplinary conference of all deaths and major complications.

43.16 The cardiac surgery program shall maintain a registry, acceptable to the Director, that collects and analyzes patient data sufficient to analyze utilization and outcome data and to determine the reasons for substantial deviations from the average utilizations and outcomes reported by nationally recognized databases. The database shall be sufficient to perform adequate risk stratification.

Reporting Requirements

43.17 Each hospital with an approved coronary artery bypass graft surgical program shall report to the Department for each hospital calendar year:

a) the number of surgical patients requiring cardiopulmonary bypass capability;

b) the number of coronary artery bypass graft surgeries by principal surgeon;

c) the number of emergency coronary artery bypass graft surgeries in the same hospital stay following percutaneous coronary intervention;

d) the inhospital mortality rate for coronary artery bypass graft surgical patients;

e) the number of coronary artery bypass graft operations by indication for performing

the surgery; and

f) such other data as specified by the Director.

Penalties for Noncompliance

43.18 The penalties for violations of the standards set forth in section 43.0 herein shall be in accordance with those set forth in Chapter 23-17 of the Rhode Island General Laws, as amended and section 7.0 herein. Failure to maintain the minimal coronary artery bypass graft surgical program standards set forth herein may result in the revocation or suspension of the hospital's coronary artery bypass graft surgical program designation and/or cessation of its activities. A hospital shall post notices for patients and shall notify physicians if its designation as an approved coronary artery bypass graft surgical program has been revoked or suspended.

Section 44.0 ***Tertiary Care Services: Heart and/or Liver Transplant Programs***

Approval to Operate a Heart and/or Liver Transplant Program and General Requirements

44.1 In order to use the designation "heart transplant program" or "liver transplant program", a hospital shall obtain approval from the Department's Division Office of Facilities Regulation. Said approval shall be issued by the Department if the heart and/or liver transplant program meets the requirements defined herein.

a) Each hospital shall renew this heart and/or liver transplant program designation annually.

44.2 Upon satisfactory review of all requested documentation and upon the determination that the hospital has achieved the volume/quality standards described herein, the Department shall approve the hospital's designation as a heart and/or liver transplant program.

44.3 A hospital that has not received approval by the Department under this section shall not use the designation "*heart transplant program*" or "*liver transplant program*", or any substantially similar phrase, to describe any such services provided and shall not perform heart and/or liver transplant procedures.

44.4 A hospital that operates a heart and/or liver transplant program approved by the Department shall maintain capabilities and provide services in accordance with the requirements described herein.

44.5 A hospital that operates a heart and/or liver transplant program approved by the Department shall maintain its membership in good standing with the United Network for Organ Sharing (UNOS).

44.6 A hospital that operates a heart and/or liver transplant program shall perform mandatory HIV testing, and counseling, as appropriate, in accordance with the HIV regulations of reference 71 herein and 42 *Code of Federal Regulations Part 486, Subpart G* (*Guidelines for*

Preventing Transmission of HIV through Transplantation of Human Tissue and Organs) (see reference 72 herein) for the prevention of HIV transmission.

44.7 A hospital that operates a heart and/or liver transplant program and determines that the heart and/or liver transplant program no longer meets minimum standards herein shall notify the Department of Health and file a plan of correction within fifteen (15) days of such determination by a hospital. The plan of correction shall be subject to the provisions of section 64.0 herein.

Minimum Standards: Volume

44.8 A new or proposed heart transplant program shall provide data showing a reasonable expectation of attaining and maintaining a minimum volume of nine (9) transplant procedures per year within two (2) years of its opening. If a second or subsequent program is proposed, it shall also report whether the addition of the new heart transplant program is likely to result in the annual volume of procedures performed by existing heart transplant programs falling below nine (9) heart transplants per year. If this outcome is likely, it will explain how the overall quality of care for all heart transplant patients in the state will be improved by the addition of the proposed program.

44.9 A new or proposed liver transplant program shall provide data showing a reasonable expectation of attaining and maintaining a minimum volume of twenty (20) transplant procedures per year within two (2) years of its opening. If a second or subsequent program is proposed, it shall also report whether the addition of the new liver transplant program is likely to result in the annual volume of procedures performed by existing liver transplant programs falling below twenty (20) liver transplants per year. If this outcome is likely, it will explain how the overall quality of care for all liver transplant patients in the state will be improved by the addition of the proposed program.

Minimum Standards: Survival Rates

44.10 Each hospital that has a heart transplant program shall maintain a record of the rates of mortality at three (3) months, one (1) year and three (3) years. Risk-adjusted rates, based on data from the UNOS database and methods acceptable to the Director of Health, shall be used. If patient or graft outcomes decline to a level mandating UNOS review, then the hospital shall notify the Department of Health and file a plan of correction.

44.11 Each hospital that has a liver transplant program shall maintain a record of the rates of mortality at three (3) months, one (1) year and three (3) years. Risk-adjusted rates, based on data from the UNOS database and methods acceptable to the Director of Health, shall be used. If patient or graft outcomes decline to a level mandating UNOS review, then the hospital shall notify the Department of Health and file a plan of correction.

Quality of Care

44.12 Each hospital that has a heart transplant program and/or a liver transplant program shall become a member of the UNOS and shall maintain its membership in good standing. The

program shall follow the procedures designated by the current bylaws of UNOS. (See reference 70 herein).

44.13 The personnel and facilities used by the transplant program shall conform to the bylaws of UNOS for heart transplantation and/or for liver transplantation, as appropriate.

44.14 The program shall document its acceptance as a member of UNOS before commencing transplantation and shall inform the Department immediately in writing if it has been notified by UNOS that the program is in jeopardy of becoming a member not in good standing.

Reporting Requirements

44.15 Each hospital that provides heart transplantation and/or liver transplantation services shall report to the Department for each hospital fiscal year:

a) the number of heart and/or liver transplants, respectively;

b) the number of heart and/or liver transplants by principal surgeon;

c) the mortality rate for heart and/or liver patients at three (3) months, one (1) year, and three (3) years.

Penalties for Noncompliance

44.16 The penalties for violations of the standards set forth in section 44.0 herein shall be in accordance with those set forth in Chapter 23-17 of the Rhode Island General Laws, as amended and section 7.0 herein. Failure to maintain the minimal heart and/or liver transplant program standards set forth herein may result in the revocation or suspension of the hospital's heart and/or liver transplant program designation and/or cessation of its activities. The hospital shall post notices for patients and notify physicians if its status as an approved heart and/or liver transplant program has been revoked or suspended.

Section 45.0 ***Tertiary Care Services: Esophageal and/or Pancreatic Cancer Surgery Programs***

Approval to Operate an Esophageal and/or Pancreatic Cancer Surgery Programs and General Requirements

45. 1 In order to use the designation "Esophageal Cancer Surgery Program" and/or "Pancreatic Cancer Surgery Program", a hospital shall obtain approval from the Department's Office of Facilities Regulation. Said approval shall be issued by the Department if the esophageal and/or pancreatic cancer surgery program meets the requirements defined herein.

a) Within six (6) months of the effective date of these regulations, any hospital operating an esophageal and/or pancreatic cancer surgery program shall file an application with the Department for approval as a "Esophageal Cancer Surgery Program" and/or "Pancreatic Cancer Surgery Program", as applicable.

b) Each hospital shall renew this esophageal and/or pancreatic cancer surgery program designation annually.

45.2 Upon satisfactory review of all requested documentation and upon the determination that the hospital has achieved the volume/quality standards described herein, the Department shall approve the hospital's designation as esophageal and/or pancreatic cancer surgery program.

45.3 A hospital that has not received approval by the Department under this section shall not use the designation "Esophageal Cancer Surgery Program" and/or "Pancreatic Cancer Surgery Program", or any substantially similar phrase, to describe any such services provided and shall not perform esophageal and/or pancreatic cancer surgery.

45.4 A hospital that operates an esophageal and/or pancreatic cancer surgery program approved by the Department shall maintain capabilities and provide services in accordance with the requirements described herein.

45.5 A hospital that operates an esophageal and/or pancreatic cancer surgery program and determines that the esophageal and/or pancreatic cancer surgery program no longer meets minimum standards herein shall notify the Department and file a plan of correction within fifteen (15) days of such determination by a hospital. The plan of correction shall be subject to the provisions of section 64.0 herein.

Minimum Standards: Volume

45.6 a) An existing esophageal cancer surgery program approved by the Department shall maintain an annual minimum volume of seven (7) operations.

b) An existing pancreatic cancer surgery program approved by the Department shall maintain an annual minimum volume of eleven (11) operations.

c) Each hospital that has an approved esophageal and/or pancreatic cancer surgery program shall participate in a nationally recognized database acceptable to the Director, if such database exists. To the extent possible, risk adjusted rates, based on data from nationally recognized databases and methods acceptable to the Director, shall be used.

45.7 a) A new or proposed esophageal cancer surgery program shall provide data to the Department showing a reasonable expectation of attaining and maintaining a minimum volume of seven (7) operations per year within two (2) years of its designation. It shall also report whether the addition of the new esophageal cancer surgery program is likely to result in the annual volume of operations performed by existing esophageal cancer surgery programs falling below seven (7) operations per year. If this outcome is likely, it will explain how the overall quality of care for all esophageal cancer patients in the state will be improved by the addition of the proposed program.

b) A new or proposed pancreatic cancer surgery program shall provide data to the Department showing a reasonable expectation of attaining and maintaining a minimum volume of eleven (11) operations per year within two (2) years of its designation. It shall also report whether the addition of the new pancreatic cancer surgery program is likely to result in the annual volume of operations performed by

existing pancreatic cancer surgery programs falling below eleven (11) operations per year. If this outcome is likely, it will explain how the overall quality of care for all pancreatic cancer patients in the state will be improved by the addition of the proposed program.

Reporting Requirements

45.8 Each hospital that provides esophageal cancer surgery and/or pancreatic cancer surgery shall report to the Department for each hospital fiscal year:

a) the number of esophageal and/or pancreatic cancer operations, respectively;

b) the number of esophageal and/or pancreatic cancer operations by principal surgeon;

c) the mortality rate for esophageal and/or pancreatic cancer patients at three (3) months, and the readmission rates.

Penalties for Noncompliance

45.9 The penalties for violations of the standards set forth in section 45.0 herein shall be in accordance with those set forth in Chapter 23-17 of the Rhode Island General Laws, as amended, and section 7.0 herein. Failure to maintain the minimal esophageal and/or pancreatic cancer surgery program standards set forth herein may result in the revocation or suspension of the hospital's esophageal and/or pancreatic cancer surgery program designation and/or cessation of its activities. The hospital shall post notices for patients and shall notify physicians, if its status as an approved esophageal and/or pancreatic cancer surgery program has been revoked or suspended.

Section 46.0 ***Special Care Units***

46.1 As used in this section, special care units may be multi-purpose or include but not be limited to units for: burn, critical care, observation, pulmonary care, rehabilitation and hemodialysis.

46.2 Special care units shall have a defined organization and shall be integrated with other departments and services of the hospital.

46.3 The units shall be designed and equipped for the defined special functions with provisions for effectiveness and safety in operation.

46.4 Hospitals shall develop and define standards for the operation of the specialized units.

46.5 The services shall be governed by written policies and procedures specifically defining admission and discharge criteria.

46.6 Each unit shall be under the direction of a physician qualified by training and experience in the specialty care.

46.7 A sufficient number of specially qualified personnel shall be provided based on the scope and complexity of the services provided.

46.8 There shall be specific written policies defining the scope of responsibilities assigned to staff personnel.

46.9 A continuing education program developed specifically for personnel of special care units shall be provided to insure an optimum level of skills and performance.

Section 47.0 ***Psychiatric Service***

47.1 Hospitals with psychiatric services shall have such services under the supervision of a clinical director who is certified by the American Board of Psychiatry and Neurology or who has equivalent training and experience.

47.2 There shall be a sufficient number of qualified professional, technical and supporting personnel and consultants to carry out a diagnostic and treatment program that includes no less than:

a) the evaluation of individual needs of patients; and

b) the establishment and implementation of written treatment and rehabilitation plans involving psychiatric, medical, surgical, nursing, social work, psychological therapies and other such services.

47.3 Medical records shall include:

a) patient's legal status;

b) psychiatric diagnosis as well as diagnoses of intercurrent diseases;

c) psychiatric evaluation which includes a medical history, records mental status, notes onset of illness and circumstances leading to admission, describes attitude and behaviors, and estimates intellectual and cognitive functioning, memory functioning and orientation;

d) complete neurological examination when indicated;

e) social service records of interviews with patient, family and others, assessments of home plans, contacts with community resources, as well as a social history;

f) treatment plans that include measurable goals and specific treatment modalities to be utilized;

g) documentation of all treatment provided;

h) at least weekly progress notes, by the physician, physician assistant, nurse, social worker, and when appropriate, others significantly involved in treatment, that provide an assessment of the patient's progress in accordance with the treatment plan;

i) discharge summary and aftercare plan.

47.4 Hospitals with psychiatric services shall maintain patient-identifiable information in confidence in accordance with all applicable state and federal statutes and regulations, including, but not limited to, Chapter 40.1-5 of the Rhode Island General Laws, as amended ("Mental Health Law") of reference 60 herein.

47.5 In addition to the above, the requirements of section 45.0 herein and all applicable sections of these regulations shall apply to a hospital providing inpatient diagnostic and therapeutic care to persons with mental disorders.

Section 48.0 ***Rehabilitation Services***

48.1 If a hospital provides rehabilitation, physical therapy, occupational therapy, audiology or speech pathology services, such services shall have a defined organizational structure with established lines of authority and responsibility that ensures accountability in patient care and administrative matters. Such services shall be integrated with other departments and services of the hospital.

48.2 The director(s) of the service or services (may be single discipline departments or multi-discipline departments) shall be qualified by training, experience, and capability to properly supervise and administer the services. The director retains responsibility for the personnel providing the service.

48.3 Services shall be provided by staff who meet the qualifications specified by the medical staff and hold current licensure, certification or registration as may be required by law (see references 54, 55, and 56 herein).

48.4 The director of the service(s) shall ensure there are a sufficient number of qualified staff to:

a) evaluate each patient requiring services;

b) initiate a plan of treatment;

c) provide treatment services;

d) instruct and supervise support staff when they are used to render services.

48.5 Services shall be provided in accordance with written orders by persons who are authorized by the medical staff to order such services. Orders shall be incorporated into the patient's clinical record.

48.6 Services shall be furnished in accordance with a written plan of treatment, which is established by the practitioner ordering the service in collaboration with an individual qualified to provide the service.

48.6.1 Treatment plans shall include treatment goals, as well as type, amount, frequency and duration of services.

48.6.2 Treatment plans shall be revised as necessary. Changes in the treatment plan shall be documented in writing and supported by clinical record information such as evaluations, test results, or orders.

48.7 Treatment shall be documented in the clinical record by the responsible person at the time services are provided. Progress notes (to note the patient's status in relationship to goal attainment) shall be recorded periodically in accordance with hospital policy.

48.8 In addition to the above, the requirements of section 46.0 and all applicable sections of the regulations contained herein shall apply to inpatient rehabilitation units.

Section 49.0 ***Substance Abuse Treatment Services/Programs***

49.1 Hospitals with substance abuse treatment programs shall have such program(s) under the direction of a physician who has experience and training in the treatment of individuals with chemical dependency.

49.2 Each program shall have a clinical supervisor to oversee counseling activities directly and provide clinical supervision. The clinical supervisor shall have a minimum of a master's degree in a clinically related field, and a minimum of three (3) years supervisory experience; be licensed as a chemical dependency clinical supervisor by the Rhode Island Board for Licensing of Chemical Dependency Professionals; or be a licensed chemical dependency professional and, at a minimum, have taken a state Department of Mental Health, Retardation, and Hospitals (MHRH)- approved course in clinical supervision.

49.3 The substance abuse program shall be staffed with a sufficient number of specially qualified professional and ancillary personnel who shall be assigned duties and responsibilities consistent with their education and experience.

49.4 There shall be sufficient number of staff to carry out the treatment program, that includes no less than:

a) initial evaluation, including medical and psychosocial assessment; and

b) the establishment and implementation of written treatment plans.

49.5 Medical records shall include:

a) Medical assessment including medical history and history of drugs prescribed;

b) History of alcohol and/or other drug use, including age of onset, duration, patterns, and consequences or resultant effects (to include medical, physical, psychosocial, employment, educational, legal, financial, family, social, recreational and other pertinent areas);

c) Special exams, tests, or evaluations necessary for complete initial and on-going assessment;

d) Individualized treatment plan, including problem list, short- and long- term goals expressed in measurable behaviors, treatment interventions, and timeframes;

e) Documentation of all treatment provided, at the time of provision;

f) At least weekly progress notes, describing progress, or lack thereof, toward goal achievement;

g) Discharge summary and aftercare plan; and

h) Post-discharge follow-up contacts.

49.6 Hospitals with substance abuse treatment programs shall maintain identifiable patient information in confidence in accordance with all applicable state and federal statutes and regulations, including, but not limited to, 42 Code of Federal Regulations of reference 59 herein.

49.7 In addition to the above, the requirements of section 45.0 and all applicable regulations contained herein shall apply to the substance abuse treatment program.

PART IV *ENVIRONMENTAL & MAINTENANCE SERVICES*

Section 50.0 ***Housekeeping and Maintenance Services***

50.1 Written housekeeping and maintenance procedures shall be established for the cleaning of all areas in the hospital based on the guidelines of reference 15. Copies shall be made available to housekeeping personnel.

50.2 All parts of the hospital and its premises shall be kept clean, neat, free of litter and rubbish, and all furnishings maintained in good repair.

50.3 Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.

50.4 Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place, and kept in an enclosed section separate from other cleaning materials.

50.5 Cleaning shall be performed in a manner which will minimize the spread of pathogenic organisms in the hospital atmosphere.

50.6 Exhaust ducts from kitchens and other cooking areas shall be equipped with proper filters and cleaned at regular intervals. The ducts shall be cleaned and inspected no less than twice a year.

Section 51.0 ***Infection Control***

51.1 The medical staff in cooperation with other disciplines shall establish a multidisciplinary group which shall report to the governing body and which shall be responsible for no less than the following:

a) establishing and maintaining a hospital-wide infection surveillance program which shall include an infection surveillance officer to conduct all infection surveillance activities;

b) developing and implementing written policies and procedures for the surveillance, prevention, and control of infections in all patient care departments/services;

c) establishing policies governing the admission and isolation of patients with known or suspected infectious diseases;

d) developing, evaluating and revising on a continuing basis infection control policies, procedures and techniques for all appropriate phases of hospital operation and services;

e) developing and implementing a system for evaluating and recording the occurrences of all infections among personnel and patients; such records shall be made available to the licensing agency upon request;

f) implementing a TB infection control program requiring risk assessment and development of a TB infection control plan; early identification, treatment and isolation of strongly suspected or confirmed infectious TB patients; effective

engineering controls; an appropriate respiratory protection program; health care worker TB training, education, counseling and screening; and evaluation of the program's effectiveness, per guidelines in reference 33.

g) developing and implementing an institution-specific strategic plan for the prevention and control of vancomycin resistance, with a special focus on vancomycin-resistant enterococci, per guidelines in reference 50.

h) developing and implementing protocols for discharge planning of patients with infectious diseases which may present the risk of continuing transmission in the community or congregate living environment. Examples of such diseases include, but are not limited to, tuberculosis (TB), Methicillin resistant *staphylococcus aureus* (MRSA), clostridium difficile, etc.

i) assuring that patient care support departments (i.e., central services, laundry, etc) are available to assist in the prevention and control of infectious diseases and are provided with adequate direction, training, staffing and facilities to perform all required infection surveillance, prevention and control functions.

51.2 Infection control provisions shall be established for the mutual protection of patients, employees and the public.

51.3 A continuing education program on infection control shall be conducted periodically for all staff.

Reporting of Communicable Diseases:

51.4 a) The hospital shall promptly report to the Rhode Island Department of Health cases of communicable diseases designated as "reportable diseases" by the Director of Health, when such cases are admitted to or are diagnosed in the hospital in accordance with the most current rules and regulations pertaining to the reporting of communicable diseases (reference 21).

b) When infectious diseases present a potential hazard to hospitalized patients or personnel, these shall be reported to the Rhode Island Department of Health, even if not designated as "reportable diseases."

c) ***Reporting by Hospital Laboratories*:** Hospital laboratories shall report communicable diseases and submit specimens in accordance with the requirements in the most current version of the *Rhode Island Epidemiological and Laboratory Reporting and Surveillance Manual* issued by the Division of Disease Prevention and Control at the Department of Health.

d) Hospitals must, in addition, comply with all other laboratory reporting requirements for TB, HIV/AIDS, sexually transmitted diseases, childhood lead poisoning and occupational diseases as outlined in reference 21.

Section 52.0 ***Laundry Service***

52.1 Each hospital shall make provisions for the cleaning of all linens and other washable goods.

52.2 Hospitals providing laundry service shall have adequate facilities and equipment for the safe and effective operation of a laundry service.

52.3 There shall be distinct areas for the separate storage and handling of clean and soiled linens. Those areas used for the storage and handling of soiled linens shall be negatively pressurized.

52.4 Special procedures shall be established for the handling and processing of contaminated linens.

52.5 All soiled linen shall be placed in closed containers prior to transportation.

52.6 To safeguard clean linens from cross-contamination they shall be:

a) transported in containers used exclusively for clean linens and shall be kept covered at all times while in transit; and

b) stored in areas designated exclusively for this purpose (e.g., linen closets, enclosed carts, etc.).

Section 53.0 ***Electromagnetic Interference and Medical Devices***

53.1 The facility's governing body, or its designee (e.g., Safety Committee), shall develop and implement policies and procedures that achieve electromagnetic compatibility, including, but not limited to, the designation of areas of the facility where the use of common hand-held radio frequency transmitters (e.g., cellular and PCS telephones, two-way radios) by staff, visitors, and/or patients is to be managed and/or restricted. Said policies and procedures shall require no less than the following:

53.1.1 Each facility shall perform an assessment of the radiated electromagnetic environment in the facility and implement the actions needed to minimize radiated electromagnetic interference and promote electromagnetic compatibility.

53.1.2 Each facility shall actively manage its equipment to foster electromagnetic compatibility and to mitigate the risks of electromagnetic interference

PART V ***PHYSICAL PLANT***

Section 54.0 ***New Construction, Addition or Modification***

54.1 All new construction, alterations, extensions or modifications of an existing facility shall be subject to the laws, rules, regulations and codes of references 17; 23; 24; 25; 26; 27; and 33; and all other appropriate state and local laws, codes, regulations, and ordinances.

54.2 Where there is a difference between codes, the code having the more stringent standard shall apply.

54.3 All plans for new construction or the renovation, alteration, extension, modification or conversion of an existing facility that may affect compliance with reference 17 herein shall be reviewed by a licensed architect, acceptable to the Director. Said architect shall certify that the plans conform to the construction requirements of reference 17 herein prior to construction. The facility shall maintain a copy of the plans reviewed and the architect's signed certification, for review by the Department of Health upon request.

54.3.1 In the event of non-conformance for which the facility seeks a variance, the general procedures outlined in section 63.0 shall be followed. Variance requests shall include a written description of the entire project, details of the non-conformance for which the variance is sought and alternate provisions made, as well as detailing the basis upon which the request is made. The Department may request additional information while evaluating variance requests.

54.3.2 If variances are granted, a licensed architect shall certify that the plans conform to all construction requirements of reference 17 herein, except those for which variances were granted, prior to construction. The facility shall maintain a copy of the plans reviewed, the variance(s) granted and the architect's signed certification, for review by the Department upon request.

54.4 Upon completion of construction, the facility shall provide written notification to the Department, describing the project, and a copy of the architect's certification. The facility shall obtain authorization from the Department prior to occupying/re-occupying the area. At the discretion of the Department, an on-site visit may be required.

54.5 In addition to the above requirements, the following requirements of sections 54.0 through 59.0 shall apply.

Section 55.0 ***Fire Safety***

55.1 Each hospital shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and such a program shall include written procedures for the implementation of said rules and regulations, and logs shall be maintained.

Section 56.0 ***Incinerators***

56.1 Incinerators within hospitals shall be segregated from other parts of the building by non-combustible construction, with walls, floors and ceilings having a fire resistance rating of not less than two hours. Openings to such rooms shall be protected by Class B fire doors, and equipped with positive self-closing devices in accordance with reference 23.

56.2 Incinerators shall be gas, electric, or oil fired and capable of destroying pathological and other types of waste.

a) An incinerator installed to handle pathological waste materials shall have the capability of completely burning the waste material and shall meet the air emission requirements of section 12.0 of reference 25.

b) Refuse incinerators shall be capable of burning rubbish containing 50 percent wet materials, and shall meet the air emission requirements of section 12.0 of reference 25.

c) A multi-purpose incinerator shall meet the requirements of both sections (a) and (b) herein.

56.3 Hospital incinerators shall be designed and installed in accordance with the air emission requirements of section 12.0 of reference 25.

Section 57.0 ***Lighting & Electrical Services***

57.1 Policies and procedures shall be established to govern the use and operation of all electrical equipment.

57.2 The standards of reference 27 shall serve as a guide to determine the lighting levels within each area of the hospital.

57.3 All electrical appliances used by hospitals shall be listed or labeled by an approved testing agency or be approved by local electrical inspection authorities.

57.4 Each hospital shall continuously evaluate (i.e., not less than every two {2} years) the essential electrical system's demand and compare that to the capacity of their emergency generation system. This evaluation shall be conducted by a qualified electrical consultant acceptable to the Director. A report on the results of the evaluation(s) shall be provided to the Director upon request.

57.5 Each hospital shall have a plan for responding to electrical system problems and failures in a timely manner. The plan shall include procedures for diagnosing and alleviating electrical problems or failures that may develop. Emergency generators and automatic transfer switches shall be tested in accordance with the most current applicable NFPA code. In addition to its own internal resources, each hospital shall also have agreements with contracted service providers for emergency services.

Section 58.0 ***Plumbing***

58.1 All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of section 27.3.3 of reference 24.

58.2 All plumbing shall be installed in such a manner as to prevent back siphonage or cross connections between potable and non-potable water supplies.

58.3 Fixtures from which grease is discharged shall be served by a line in which a grease trap is installed. The grease trap shall be cleaned sufficiently often to sustain efficient operation.

Section 59.0 ***Waste Water Disposal***

59.1 Any new facility shall be connected to a public sanitary sewer.

Section 60.0 ***Waste Disposal***

Medical Waste:

60.1 Medical waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste* (*DEM-DAH-MW-01-92*, April 1994), Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

Other Waste:

60.2 Wastes which are not classified as medical waste, hazardous wastes or which are not otherwise regulated by law or rule may be disposed in dumpsters or load packers provided the following precautions are maintained:

a) Dumpsters shall be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply shall be available within easy accessibility for washing down of the area. In addition, the pick-up schedule shall be maintained with more frequent pick-ups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.

b) Load packers must conform to the same restrictions required for dumpsters and, in addition, load packers shall be:

i. high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment; and

ii. the loading section shall be constructed and maintained to prevent rubbish from blowing from said area site.

Section 61.0 ***Water Supply***

61.1 Water shall be obtained from a community water system as defined in section 1.3 of reference 31.

61.2 The water shall be distributed to conveniently located taps and fixtures throughout the buildings and shall be adequate in volume and pressure for all hospital purposes, including fire fighting.

Section 62.0 ***Existing Structures***

62.1 In all instances, where exceptions are not granted by the licensing agency, the same standards as specified for new construction shall apply.

PART VI *CONFIDENTIALITY, VARIANCE & SEVERABILITY*

Section 63.0 *Confidentiality*

63.1 Disclosure of any health care information relating to individuals shall be subject to the provisions of all relevant statutory and federal requirements governing confidentiality of health care information including but not limited to the provisions of reference 38.

Section 64.0 *Variance Procedure*

64.1 The licensing agency may grant a variance upon request of the applicant from the provisions of any rules and regulations herein, if it finds in specific cases, that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest.

64.2 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.

64.2.1 Upon filing of each request for variance with the licensing agency and within a reasonable time thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial. Such hearing must be held in accordance with the provisions of section 66.0 herein.

Section 65.0 *Deficiencies & Plans of Correction*

65.1 The licensing agency shall notify the governing body or other legal authority of a facility of violations of individual standards through a notice of deficiencies which shall be forwarded to the facility within fifteen (15) days of inspection of the facility unless the Director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with section 23-1-21 of the General Laws of Rhode Island, as amended.

65.2 A facility which received a notice of deficiencies must submit a plan of correction to the licensing agency within fifteen (15) days of the date of the notice of deficiencies.

65.3 The licensing agency will be required to approve or reject the plan of correction submitted by a facility in accordance with section 65.2 above within fifteen (15) days of receipt of the plan of correction.

65.4 If the licensing agency rejects the plan of correction, or if the facility does not provide a plan of correction within the fifteen (15) day period stipulated in section 65.2 above, or if a facility whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in section 7.0 herein. If the facility is aggrieved by the sanctions of the licensing agency, the facility may appeal the decision and request a hearing in accordance with Chapter 42-35 of the General Laws.

65.5 The notice of the hearing to be given by the Department of Health shall comply in all respects with the provisions of Chapter 42-35 of the General Laws. The hearing shall in all respects comply with the provisions therein.

Section 66.0 ***Rules Governing Practices & Procedures***

66.1 All hearings and reviews required under the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health* (*R42-35-PP*) of reference 39.

Section 67.0 ***Severability***

67.1 If any provision of these regulations or the application thereof to any facility or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

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Tuesday, 31 July 2012

PART VII ***REFERENCES***

1. "Administrative Procedures Act", Chapter 42-35 of the General Laws of Rhode Island, as amended.

2. *Food Code (R23-1, 21-27-FOOD)*, Office of Food Protection, Rhode Island Department of Health, October 2007 and subsequent amendments thereto.

3. "Recommended Dietary Allowances", National Research Council, National Academy of Sciences, 2101 Constitution Avenue, Washington, D.C. 20418.

4. *Rules and Regulations Pertaining to Sanitary Standards for Manufacture, Processing, Storage and Transportation of Ice (R23-1-I)*, Rhode Island Department of Health, June 1966 and subsequent amendments thereto.

5. *Rules and Regulations Pertaining to Frozen Food Products (R-23-1-FF1)*, Rhode Island Department of Health, July 1966 and subsequent amendments thereto.

6. "Mobile Intensive Care Unit Program", Chapter 23-17.6 of the General Laws of Rhode Island, as amended.

7. *Health Care Facilities: Hospital Laboratories, NFPA 99 Standards*, National Fire Protection Association, One Battery March Park, P.O. Box 9101, Quincy, MA 02269-9101.

8. *Standards for a Blood Transfusion Service*, American Association of Blood Banks, 30 North Michigan Avenue, Chicago, Illinois 60606.

9. *Accreditation Manual for Hospitals*, Joint Commission on Accreditation of Health Care Organizations, One Renaissance Boulevard, Oakbrook Terrace, IL 60181.

10. *Protection of Records*, National Fire Protection Association, One Battery March Park, P.O. Box 9101, Quincy, MA 02269-9101.

11. "Vital Statistics", Section 23-3-26 of the General Laws of Rhode Island, as amended.

12. "Title 10 Parts 19, 20 and 35 of the Code of Federal Regulations", United States Nuclear Regulatory Commission, Washington, D.C.

13. "Pharmacy", Chapter 5-19.1 of the General Laws of Rhode Island, as amended.

14. *Rules and Regulations for the Control of Radiation*, Division of Occupational and Radiological Health, Rhode Island Department of Health, September 2007 and subsequent amendments

    thereto.

15. *Health Care Environmental Services: Housekeeping Departmental Training Manual*, 1996, American Hospital Association, 840 North Lake Shore Drive, Chicago, IL 60611 (1-800-242-2626, catalogue #197101).

16. *Health Care Facilities: Flammable Anesthetics, NFPA 99 Standards*, National Fire Protection Association, One Battery March Park, P.O. Box 9101, Quincy, MA 02269-9101.

17. *Guidelines for Design and Construction of Hospital and Health Care Facilities*, The American Institute of Architects Academy of Architecture for Health with Assistance from

the U.S. Department of Health and Human Services. Washington, D.C.: The American Institute of Architects Press, 2006.

18. "Maternal and Child Health", Section 23-13-1 through Section 23-13-12, General Laws of Rhode Island, as amended.

19. *Standards and Recommendations for Hospital Care of Newborn Infants*, American Academy of Pediatrics, 1801 Hinman Avenue, Evanston, IL 60204.

20. *Standards for Obstetric-Gynecological Hospital Services*, The American College of Obstetricians and Gynecologists, 79 West Monroe Street, Chicago, IL 60603.

21. *Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (R23-10-DIS*), Rhode Island Department of Health, August 2008 and subsequent amendments thereto.

22. "Licensing of Health Care Facilities", Chapter 23-17 of the General Laws of Rhode Island, as amended.

23. "Rhode Island State Fire Safety Code", Chapter 23-28-1 of the General Laws of Rhode Island, as amended.

24. "The Rhode Island State Building Code", Chapter 23-27.3 of the General Laws of Rhode Island, as amended.

25. *Rules and Regulations for the Prevention, Control and Abatement and Limitation of Air Pollution,* Rhode Island Department of Environmental Management.

26. *The National Fire Codes*, National Fire Protection Association, One Battery March Park, P.O. Box 9101, Quincy, MA 02269-9101.

27. *Lighting for Hospitals*, Illuminating Engineering Society, 345 East 47th Street, New York, NY 10017.

28. *Rules and Regulations for the Termination of Pregnancy*, Rhode Island Department of Health, January 2002 and subsequent amendments thereto.

29. "Approval of Construction by Director", Section 23-1-31 of the General Laws of Rhode Island, as amended.

30. *Rules and Regulations Pertaining to Medical Examiner System*, Rhode Island Department of Health, September 2007 and subsequent amendments thereto.

31. *Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ)*, Rhode Island Department of Health, May 2008 and subsequent amendments thereto.

32. *Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions as Low as Reasonably Achievable*, Office of Standards Development, United States Nuclear Regulatory Commission.

33. *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities*, 1994, U.S. Department of Health & Human Services, Public Health Service, Centers for Disease Control & Prevention, October 28, 1994, vol. 43, no. RR-13.

34. *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services (R23-15-CON),* Rhode Island Department of Health, August 2008 and subsequent amendments thereto.

35. *Rules and Regulations for Licensing of Midwives (R23-13-MID)*, Rhode Island Department of Health, September 2007 and subsequent amendments thereto.

36. *Rules and Regulations for Licensing Birth Centers (R23-27-BC)*, Rhode Island Department of Health, March 2005 and subsequent amendments thereto.

37. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, April 1994 and subsequent amendments thereto.

38. "Confidentiality of Health Care Information," Chapter 5-37.3 of the General Laws of Rhode Island, as amended.

39. *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*, Rhode Island Department of Health, April 2004 and subsequent amendments thereto.

40. "Uniform Anatomical Gift Act", Chapter 23-18.6 of the General Laws of Rhode Island, as amended.

41. *Rules and Regulations Governing the Disposal of Legend Drugs (R21-31-LEG)*, Rhode Island Department of Health, January 2002 and subsequent amendments thereto.

42. *Rhode Island EMS Prehospital Care Protocols & Standing Orders*, Rhode Island Department of Health, July 1995 and subsequent amendments thereto.

43. "Admission of Patient Generally--Rights of Patients-Patients' Records--Competence of Patients", Chapter 40.1-5-5. of the General Laws of Rhode Island, as amended.

44. "Mammography Quality Standards Act of 1992", Title 42 U.S. Code, Section 263b, pp. 595-610, 1994.

45. "Blood Borne Pathogens", Occupational Safety and Health Administration (OSHA), 29 CFR Part 1910-1000 to end, section 1910.1030, pp. 316-326, July 1, 1994.

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APPENDIX "A"
Universal Perinatal Screening Protocol

DISCHARGE AFTER DELIVERY OF A NORMAL NEWBORN

A perinatal hospitalization is unique in that proper medical care involves two patients at the beginning of a crucial long-term relationship. The medically necessary care of the mother and infant at birth includes the assessment, documentation and management of patient needs in the domains of maternal health, infant health and development and nurturance. Early perinatal discharge is only appropriate if an assessment is complete, all significant patient needs have been addressed and a mechanism is in place to ensure follow-up. Discharge of mothers and infants should be coordinated so that the pair leave the hospital together, unless the medical condition of one requires a significantly longer hospital stay.

The following risk factors shall be evaluated and appropriate follow-up care plans and/or referrals documented in the medical record prior to discharge.

MATERNAL HEALTH:

- ☐ The mother has stable vital signs, is ambulatory, eating and voiding;
- ☐ The uterus is firm, the perineum intact or sutured and there is no significant active post-partum bleeding;
- ☐ Post-partum exam and lab work completed, treatment and instructions given;
- ☐ Rhogam and/or rubella vaccine given, if required;
- ☐ Other maternal health problems documented and addressed.

INFANT HEALTH & DEVELOPMENT:

- ☐ Successful feeding x 3, voiding and defecating;
- ☐ Vital signs stable for at least 12 hours;
- ☐ Physical examination completed;
- ☐ Metabolic, hemoglobinopathy, Level 1, and hearing screening and other lab work completed;
- ☐ Eye prophylaxis, hepatitis B vaccine and Vitamin K given as required;
- ☐ Other infant health and development issues documented and addressed, parent instructions given, follow-up appointments arranged;
- ☐ Birth certificate completed.

If the infant weighs less than 2,500 grams or has a 5-minute APGAR score less than seven, or if the mother is known to have a risk factor (e.g., diabetes, streptococcal carrier, hepatitis or illicit drug use) for early post-natal complications, discharge in less than 48 hours after birth may be contraindicated.

NURTURANCE:

- There is a responsible adult available to assist the mother and infant at home for at least twenty-four hours;
- There is a telephone in the home, and a caregiver who speaks the mother's language is available to provide telephone assistance;
- The home is reasonably safe, food, and heat if needed, is available;
- Appointments for follow-up care are complete, including home visits, family support referrals and primary care visits;
- If the mother is under 17 years of age, has less than a high school education, has other impairments, a history of neglect or other significant risk for poor nurturance or developmental problems such as those identified by Universal Level 1 Newborn Screening, appropriate family support arrangements have been completed.