Rhode Island Department of Health
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Providence, RI 02908-5094

www.health.ri.gov

To: Members of the Community Interested in the:
***Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services* [*R23-15-CON*]**

From: Michael K. Dexter, MPA, Chief
Office of Health Systems Development

Date: 5 November 2010

Attached for your review and comment are proposed **draft** amendments to the ***Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services* [*R23-15-CON*].** These amendments are proposed in accordance with the provisions of Public Laws 2009-287 and 2009-197, which require the Department of Health to identify additional categories of equipment/services which are now subject to the Certificate of Need (CON) review process. The proposed **draft** amendments also address "housekeeping" changes in these Regulations.

Because of your interest and expertise in these matters, the Department would appreciate your review of the proposed **draft** amendments. An ***informal*** community review meeting has been scheduled on this matter for **Wednesday, 17 November 2010** at **2:00 p.m.** in the **Auditorium** of the Cannon Building (on the lower level).

If you have any questions about the proposed **draft** amendments, or if you wish to submit written comments in advance of the meeting, please direct them to Michael K. Dexter, MPA, Chief, Office of Health Systems Development: Michael.Dexter@health.ri.gov or 401-222-2788.

Please feel free to circulate additional copies of this document, as needed, to any interested person. Upon request, for persons with disabilities, copies of these proposed regulations are also available in Braille, large print, audio cassette, and electronic file (computer disk). Please call 401-222-7767 or RI Relay 711 if you need such assistance. For your reference, these proposed regulations also appear on the Department's website**: http://www.health.ri.gov/regulations/** and the Secretary of State's Open Meeting website:

Your participation is appreciated. Thank you.

Attachment

COMMUNITY REVIEW DRAFT – REVISED 4 NOVEMBER 2010

RULES AND REGULATIONS FOR DETERMINATION OF NEED FOR NEW HEALTH CARE EQUIPMENT AND NEW INSTITUTIONAL HEALTH SERVICES

[R23-15-CON]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

June 1979

AS AMENDED

February 1981
August1981 (E)
December 1981 (E)
February 1982
August1982 (E)
October 1982
February 1984
February 1984 (E)
June 1984
September 1984 (E)
January 1985 (E)
February 1985
March 1986
September 1986
December 1987
December 1988 (E)
July 1990 (E)
July 1990
November 1990 (E)
November 1991 (E)
February 1992 (E)
April 1992
November 1994 (E)
March1995 (E)
May 1995
July 1995 (E)
November 1995 (E)
February 1996
October 1997
July 1999 (E)
November 1999 (E)
January 2000
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
January 2007
August 2008
December 2010 (Proposed)

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

INTRODUCTION

These amended *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services* [*R23-15-CON*] are promulgated pursuant to the authority conferred under RIGL Chapters 23-15 and 42-35 ~~of the Rhode Island General Laws, as amended~~, and are established for the purpose of establishing prevailing standards and procedures regarding the determination of need for the development of new health care equipment and new institutional health services.

Pursuant to the provisions of ~~section~~ RIGL §42-35-3(c) ~~of the General Laws of Rhode Island, as amended~~, the following were given consideration ~~was given~~ in arriving at the amended regulations ~~to~~: (1) alternative approaches to the regulations; and (2) duplication or overlap with other state regulations. Based on the available information, no known overlap, duplication, or alternative approach ~~has been~~ was identified.

Upon promulgation of these amendments, these amended ~~rules and~~ regulations shall supersede all previous *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services* promulgated by the Rhode Island Department of Health and filed with the ~~Rhode Island~~ Secretary of State.

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Section 1.0 ***Declaratory Rulings***

1.1 As prescribed by ~~section~~ RIGL §42-35-8 ~~of the Rhode Island General Laws, as amended~~, any interested person may petition the Director for a declaratory ruling. Each petition shall state clearly and concisely the specific issues to be considered and the facts relevant and applicable thereto, and any additional information required by applicable statutes and regulations. The Director, or his/her designee, shall consider the petition and within a reasonable time shall:

1. Issue a declaratory ruling; or
2. Notify the petitioner that no declaratory ruling is to be issued; or
3. If requested by a petitioner, or at the discretion of the Director, or his/her designee, set a reasonable time and place for hearing argument upon the matter, and give reasonable notice to the parties of the time and place for such hearing. After said hearing is conducted, the Director or his/her designee shall, within a reasonable time, issue a declaratory ruling.

Section 2.0 ***Review Requirement***

2.1 No health care facility or health care provider shall develop or offer new health care equipment as defined ~~herein~~ in these Regulations without prior review by the Health Services Council and approval by the state agency.

2.2 (a) No health care facility or health care provider shall develop or offer new institutional health services as defined ~~herein~~ in these Regulations without prior review by the Health Services Council and approval by the state agency. ~~unless an exemption has been granted under section 2.7 herein.~~

(b) Acquisition of full body magnetic resonance imaging and computerized axial tomography equipment after 1 January 2010, and the acquisition of other health care equipment listed in §3.33 of these Regulations, shall require prior certificate of need review and approval by the state agency.

(c) Acquisition of full body magnetic resonance imaging and computerized axial tomography equipment shall not require a certificate of need review and approval by the state agency if satisfactory evidence is provided to the state agency that the full body magnetic resonance imaging or computerized axial tomography equipment was acquired for under one million dollars ($1,000,000) on or before 1 January 2010 and was in operation on or before 1 July 2010.

(d) The word "acquisition" as used in §2.2 of these Regulations shall mean and include acquisition by purchase, sale, joint venture, transfer of title and property, asset purchase, lease, transfer of shares of corporate stock which results in a new person acquiring a controlling interest in such corporation, change in membership which results in a new person acquiring a controlling vote in such non-business corporation or in the case of a partnership the removal, addition or substitution of a partner which results in a new partner acquiring a controlling interest in the partnership.

2.3 Only proposals for new health care equipment or new institutional health services as defined ~~herein~~ in these Regulations which are found by the state agency to be both needed and affordable shall be granted approval by the state agency.

2.4 No health care facility shall develop or offer new institutional health services as defined ~~herein~~ in these Regulations if approval for such services has been withdrawn by the state agency in accordance with ~~section~~ §15.0 ~~herein~~ of these Regulations.

2.5 No person may incur an obligation for a capital expenditure for a new institutional health service or new health care equipment without obtaining approval for the capital expenditure. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility or health care provider:

(a) When a contract, enforceable under Rhode Island law, is entered into by or on behalf of the health care facility or health care provider for the construction, acquisition, lease or financing of a capital asset; or

(b) When the governing board of a health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

(c) In the case of donated property, on the date on which the gift is completed in accordance with Rhode Island law.

(d) For the purposes of ~~section~~ §2.5 ~~herein~~ of these Regulations, an obligation for a capital expenditure which is contingent upon issuance of a certificate of need is not incurred until the certificate of need is issued.

2.6 A certificate of need is required as a precondition to licensure of any new health care facility or to the establishment of any additional inpatient health care facility or any additional surgicenter premises of a health care facility.

2.7 Any provider of hospice care who provides such hospice care without charge shall be exempt from the provisions of ~~this Chapter~~ the Act.

2.8 ~~The state agency, upon prior receipt of written notification on the state agency's form,~~ Any application for one for one equipment replacement exemption must be submitted on a written form provided by the state agency and acceptable to the state agency and must be supplemented with an agreement that has been executed with the Director for the payment of all costs and expenses in accordance with §4.1(f) of these Regulations, After consideration, the state agency shall exempt from review any application which proposes "one for one equipment replacement" as defined ~~herein~~ in these Regulations. An exemption for one for one replacement of full body magnetic resonance imaging or computerized axial tomography shall not require that the full body magnetic resonance imaging or computerized axial tomography equipment to be replaced had been the subject of a prior certificate of need approval.

Section 3.0 ***Definitions***

3.1 "***Accelerated review***" means a shortened certificate of need review of a proposal which the

state agency has identified and preliminarily determined to present a prima facie demonstration of public need and affordability.

3.2 "***Act***" means RIGL Chapter 23-15 entitled "*Health Care Certificate of Need Act of Rhode Island*".

~~3.2~~ 3.3 "***Administrative review agency***" means the agency designated by the Director in accordance with ~~section~~ §23-15-6(b)(10) of the ~~Rhode Island General Laws, as amended,~~ Act to conduct administrative reviews when requested by persons directly affected by decisions of the state agency in accordance with ~~section~~ §17.0 of these Regulations ~~herein~~.

~~3.3~~ 3.4 "***Affected persons***", for purposes of these Regulations ~~herein~~, means and includes, but is not limited to, the person whose proposal is being reviewed, or the applicant; health care facilities located within the state which provide institutional health services; the state medical society; the state osteopathic society; the medical school; such voluntary non-profit area-wide planning agencies as may be established in the state; statutory planning bodies; the state budget office, the Office of the Health Insurance Commissioner, and hospital or medical service corporation organized under the laws of the state; and those members of the public who are to be served by the proposed new institutional health services or new health care equipment.

~~3.4~~ 3.5 "***Affordability***" means the relative ability of the people of the state to pay for or incur the cost of a proposal, given:

(a) Consideration of the condition of the state's economy;

(b) Consideration of the statements of authorities and/or parties affected by such proposals;

(c) Economic, financial, and/or budgetary constraints of parties affected by such proposals, including cost impact statements submitted by the State Medicaid Agency or State Budget Officer;

(d) Other factors deemed relevant by the Health Services Council or the Director.

~~3.5~~ 3.6 "***Clinical health services***" means one or more organized program components for preventive, assessment, maintenance , diagnostic, treatment and rehabilitative services, provided in a health care facility.

~~3.6~~ 3.7 "***Construction***" means the erection, building, renovation, replacement or alteration of the physical plant of a health care facility.

~~3.7~~ 3.8 "***Cost impact analysis***" means a written analysis of the effect that a proposal to offer or develop new institutional health services or new health care equipment, if approved, will have on health care costs and shall include, but not be limited to, consideration of the proposal's effects on increases in operating expenses, per diem rates, health care insurance premiums, Medicaid reimbursement, and public health expenditures.

~~3.8~~ 3.9 "***Director***" means the Director of the Rhode Island Department of Health.

~~3.9~~ 3.10 "***Equity***" means non-debt funds contributed towards the capital cost of an acquisition or project which are free and clear of any repayment obligation or liens against assets, and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.

~~3.10~~ 3.11 "***Health care facility***" means any institutional health service provider, facility or institution, place, building, agency, or portion thereof, whether a partnership or corporation, whether organized for profit or not, used, operated, or engaged in providing health care services, which are limited to hospitals, nursing facilities, inpatient rehabilitation centers ~~(including drug and/or alcohol abuse treatment centers licensed pursuant to Chapter 40.1-1 of the General Laws)~~, certain facilities providing surgical treatment to patients not requiring hospitalization (surgicenters, multi-practice physician ambulatory surgery centers and multi-practice podiatry ambulatory surgery centers) and facilities providing inpatient hospice care.

Single-practice physician or podiatry ambulatory surgery centers (as defined in RIGL §23-17-2(13) and §23-17-2(14) respectively) are exempt from the requirements of the Act; provided that such exemption shall not apply if a single-practice physician or podiatry ambulatory surgery center is established by a medical practice group (as defined in RIGL §5-37-1) within two (2) years following the formation of such medical practice group, when such medical practice group is formed by the merger or consolidation of two (2) or more medical practice groups or the acquisition of one medical practice group by another medical practice group.

The term "health care facility" does not include Christian Science institutions (also known as Christian Science Nursing Facilities) listed and certified by the Commission for Accreditation of Christian Science Nursing Organizations/Facilities, Inc.

~~3.11~~ 3.12 "***Health care provider***" means a person who is a direct provider of health care services (including but not limited to physicians, dentists, nurses, podiatrists, physician assistants or nurse practitioners) in that the person's primary current activity is the provision of health care services for persons.

~~3.12~~ 3.13 "***Health Services Council***" means the advisory body to the Rhode Island Department of Health established in accordance with RIGL Chapter 23-17 ~~of the Rhode Island General Laws, as amended~~, appointed and empowered to serve as the advisory body to the state agency in its review functions under the Act ~~Chapter 23-15 of the Rhode Island General Laws, as amended~~.

~~3.13~~ 3.14 "***Hospital***" shall have the same meaning as defined in the *Rules and Regulations for Licensing of Hospitals*, Rhode Island Department of Health of reference 1.

~~3.14~~ 3.15 "***Inpatient hospice care***" shall have the same meaning as defined in the *Rules and Regulations for Licensing Hospice Care* (*R23-17-HCP*), promulgated by the Rhode Island Department of Health, of reference 4.

~~3.15~~ 3.16 The term "***inpatient rehabilitation center***" shall have the same meaning as defined in the *Rules and Regulations for Licensing Rehabilitation Hospital Centers, Rhode Island Department of Health*, of reference 2, established pursuant to RIGL Chapter 23-17 ~~of the Rhode Island General Laws, as amended~~.

~~3.16~~ 3.17 "I***nstitutional health services***" means health services provided in or through health care facilities and includes the entities in or through which such services are provided.

~~3.17~~ 3.18 "***New health care equipment***" means any single piece of medical equipment (and any components which constitute operational components thereof) proposed to be utilized ~~by a health care facility or health care provider (whether practicing alone or as a member of a partnership, corporation, organization or association)~~ in conjunction with the provision of

services to patients or the public, the capital costs of which (including acquisition under lease or comparable arrangement or through donation) would exceed one million dollars ($1,000,000).

~~3.18~~ 3.19 "***New institutional health services***" means and includes:

(a) Construction, development, or other establishment of a new health care facility.

(b) Any expenditure (except acquisitions of an existing health care facility which will not result in a change in the services or bed capacity of such health care facility, as defined in §3.19(b)(3) of these Regulations) by or on behalf of an existing health care facility in excess of two million dollars ($2,000,000) which is a capital expenditure, including expenditures for predevelopment activities.

(1) The term capital expenditure includes all expenditure of funds (whether by purchase or lease) not properly chargeable as expenses of operation and maintenance, which is associated with the provision of a health service or related to a unified plan of renovation or construction or development, including equipment proposed to be offered or undertaken during the course of any twelve (12) month period where the total of such expenditures exceeds two million dollars ($2,000,000).

(2) The term capital expenditure includes the cost of studies, surveys, designs, plans, working drawings, and specifications, as well as expenditures directly or indirectly related to capital expenditures such as grading, paving, broker commission, taxes assessed during the construction period, costs involved in demolishing or razing structures on land, title fees, permit and license fees, architect, legal, accounting and appraisal fees, capitalized interest, and other costs incurred for borrowing funds. In short, the total estimated cost of all elements or components of a functional facility including land, plant, building or equipment (whether purchased or leased) for providing services to health care facility patients, personnel, or the visiting public are included in the term capital expenditure.

(3) Capital expenditures include obligations of capital expenditures by any person to acquire an existing health care facility if such capital expenditure, as provided for in the acquisition document(s), will result in a change in ~~the notice of intent required in accordance with section 5.0 herein is not filed or if the state agency finds, within thirty (30) days after the date it received notice in accordance with section 5.0 herein, that~~ the service or bed capacity of the facility ~~will be changed~~ in any of the following ways in being acquired:

(a) Change in bed capacity which increases the total number of beds; or

(b) Change in service, as defined in §3.19(e) or §3.19(f) of these Regulations. ~~bed capacity which redistributes beds among discrete services (e.g., obstetrics, pediatrics, medical, surgical) or levels of care (e.g., intensive coronary, special, post acute, skilled nursing, intermediate, rehabilitative) or relocates beds from one physical facility or site to another by ten (10) beds or10%, whichever is less, in any two year period; or~~

~~(c) The addition of a health service not provided in or through the facility throughout the previous twelve (12) months, or~~

~~(d) The termination of a health service provided in or through the facility~~.

(4) Where a person makes an acquisition by or on behalf of a health care facility, or health maintenance organization or other person under lease or comparable arrangement or through donation, which would have required review if the acquisition had been by purchase, such acquisition shall be deemed a capital expenditure subject to review. An acquisition for less than fair market value must be reviewed if the acquisition at fair market value would be subject to review under ~~paragraph (b) of this section~~ §3.18(b) of these Regulations.

(5) Where a person makes an expenditure for predevelopment activities, as defined ~~herein~~ in these Regulations, which exceeds two million dollars ($2,000,000) or the pertinent time period, such expenditure shall be deemed a capital expenditure subject to review. Approval of expenditures only for predevelopment activities will not authorize the offering or development of or preclude subsequent review of the new institutional health service with respect to which such predevelopment activities are proposed. Expenditures for predevelopment activities which do not exceed two million dollars ($2,000,000) and approved expenditures for predevelopment activities which do exceed two million dollars ($2,000,000) where the associated new institutional health service is subsequently denied, will not be subject to the sanctions outlined in ~~section~~ §23-15-4(h) of the ~~General Laws~~ Act.

(c) Except for licensed nursing facilities, any capital expenditure which increases the total number of beds in a health care facility with respect to which the expenditure is made.

(d) Licensed nursing facilities shall be exempt from review for increases in licensed bed capacity that do not exceed ten (10) beds or ten percent (10%) of facility licensed bed capacity, whichever is greater, during any twelve (12) month period, provided that the capital expenditure associated with any such increases do not exceed two million dollars ($2,000,000). Any bed increase sought under this exemption must demonstrate to the state agency full and satisfactory compliance with the requirements for the *Rules and Regulations for Licensing of Nursing Facilities* (*R23-17-NF*) of reference 5. The twelve (12) month time frame for each nursing facility under this exemption shall commence on the date specified in the state agency's approval of any increase in bed capacity.

(e) Any health service, proposed to be offered to patients or the public by a health care facility, which was not offered on a regular basis by or on behalf of said facility throughout the twelve (12) month period prior to the time such service would be offered and which exceeds seven hundred and fifty thousand dollars ($750,000) in annualized operating costs (including but not necessarily limited to salaries, wages, supplies, depreciation, and interest) as defined ~~herein~~ in these Regulations.

(f) Any new or expanded tertiary or specialty care service, regardless of capital expense or operating expense, as defined in ~~section 3.31~~ §3.33 of these Regulations.

~~3.19~~ 3.20 "***Non-clinical proposal***" means any capital expenditure by or on behalf of a health care facility, exempted pursuant ~~section~~ §6.0 ~~herein~~ of these Regulations, that is not directly related to the provision of clinical health services or patient care activities including but not limited to parking lots, information systems, and telephone systems.

~~3.20~~ 3.21 The term "***nursing facility***" shall have the same meaning as defined in the *Rules and*

Regulations for Licensing of Nursing Facilities (*R23-17-NF*) promulgated by the Rhode Island Department of Health of reference 5 ~~herein~~ of these Regulations.

~~3.21~~ 3.22 "***One for one equipment replacement***" means the replacement of health care equipment wherein the new health care equipment will not significantly alter the purpose, function, or clinical applications of the health care equipment to be replaced and shall include, but not be limited to, ~~cardiac catheterization, positron emission tomography (PET) or positron emission tomography-computerized tomography (PET-CT), and linear accelerators~~ health care equipment listed in §3.33 of these Regulations.

~~3.22~~ 3.23 The term "***person***" means any individual, trust or estate, partnership, corporation, (including associations, joint stock companies, limited liability corporations and insurance companies) state, or political subdivision or instrumentality of a state or any legal entity.

~~3.23~~ 3.24 "***Predevelopment activities***" means expenditures for architectural designs, plans, working drawings and specifications, site acquisition, professional consultations, preliminary plans, studies, and surveys necessary for the preparation of an application for the offering of a new institutional health service.

~~3.24~~ 3.25 "***Premises***" means a tract of land and the buildings thereon where direct patient care services are provided.

~~3.25~~ 3.26 "***Public need***" means a substantial or obvious community need for the specific new health care equipment or new institutional health service proposed and the scope thereof, in light of the attendant circumstances and in the context of the considerations outlined in ~~section~~ §§ 4.3(d) and 9.12 ~~herein~~ of these Regulations.

~~3.26~~ 3.27 "***Request for Proposals***" (***RFP***) means a public notice duly issued by the state agency which indicates that the state agency has identified, on a preliminary basis, the potential need for development or expansion of a particular institutional health service or new health care equipment and that the state is soliciting proposals addressing such potential need from prospective applicants.

~~3.27~~ 3.28 "***Research proposal***" means any formal scientific investigation in basic biomedical or medical research areas undertaken by or on behalf of a health care facility, exempted pursuant to ~~section~~ §7.0 ~~herein~~ of these Regulations, that is not directly related to the offering of clinical health services or patient care activities.

3.29 "***RIGL***" means the General Laws of Rhode Island, as amended.

~~3.28~~ 3.30 "***State agency***" means the Rhode Island Department of Health.

~~3.29~~ 3.31 "***State health plan***" means such plan or plans as may be developed pursuant to ~~section~~ RIGL §§23-1-1.1, 23-1-1.2 and RIGL Chapter 23-81 ~~of the Rhode Island General Laws, 1956, as amended,~~ specifying the health goals for the state on the basis of the characteristics, resources and special needs of the state and its population.

~~3.30~~ 3.32 "***Surgicenters***" shall have the same meaning as defined in the *Rules and Regulations for Licensing of Freestanding Ambulatory Surgical Centers*, Rhode Island Department of Health, of reference 3.

~~3.32~~ 3.33 "***Tertiary or specialty care services or equipment***" means, for reasons of quality, access, efficiency or cost, cardiac catheterization, positron emission tomography (PET)/positron

emission tomography-computerized tomography (PET-CT), linear accelerators (including CyberKnife and proton therapy units), open heart surgery, organ transplantation, full body magnetic resonance imaging, computerized axial tomography (excluding cone beam and dental) and neonatal intensive care services. For the purpose of this review requirement, an expansion of an existing tertiary or specialty care service or equipment involving capital and/or operating expenses for additional equipment or facilities is reviewable; provided, however, that caseload volume increases associated with more efficient utilization for existing equipment and facilities shall not be deemed subject to review as an expanded tertiary or specialty care service.

3.34 "***These Regulations***" mean all parts of the Rhode Island *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Care Services* [*R23-15-CON*].

~~3.32~~ 3.35 "***To develop***" means to undertake those activities which, on their completion, will result in the offering of a new institutional health service or new health care equipment or the incurring of a financial obligation, in relation to the offering of such a service or equipment.

~~3.33~~ 3.36 "***To offer***" means to hold oneself out as capable of providing, or as having the means for the provision of, specified new institutional health services or new health care equipment.

Section 4.0 ***Formal Application***

4.1 Application forms required of applicants will include but not be limited to items noted in ~~section~~ §4.3 ~~herein~~ of these Regulations and such additional information as may be deemed appropriate by the state agency. The state agency requires that an application fee be included with the materials filed for certificate of need review. Application fees shall be non-refundable. The application fee shall be paid by check made payable to the General Treasurer.

(a) Except for applications that propose new or expanded tertiary or specialty care services, the submission of any application filed in accordance with ~~section~~ §23-15-4(d) of the Act by any applicant ~~except a health care facility owned and operated by the state of Rhode Island,~~ shall include an application processing fee of five hundred dollars ($500) per application plus an amount equal to one quarter of one percent (0.25%) of the total capital expenditure costs associated with the application. ~~except that~~ However, a health care facility owned and operated by the state of Rhode Island shall be exempt from this application fee.

(b) Except for applications that propose new or expanded tertiary or specialty care services, for any application filed in accordance with requirements of §23-15-5 (Expeditious Review) of the Act, any applicant ~~except a health care facility owned and operated by the state of Rhode Island,~~ shall include an application processing fee of seven hundred and fifty dollars ($750) per application plus an amount equal to one quarter of one percent (0.25%) of the total capital expenditure costs associated with the application. However, a health care facility owned and operated by the state of Rhode Island shall be exempt from this application fee.

(c) Applications that propose new or expanded tertiary or specialty care services as identified in §3.33 of these Regulations ~~section 3.31 herein, except for any application~~

~~from a health care facility owned and operated by the state of Rhode Island,~~ shall include an application fee of ten thousand dollars ($10,000) plus an amount equal to one quarter of one percent (0.25%) of the total capital expenditure costs associated with the application. However, a health care facility owned and operated by the state of Rhode Island shall be exempt from this application fee.

(d) If during the course of review the capital cost of a proposal is increased as a result of a formal modification of the proposal which is accepted by the state agency, the applicant shall submit a supplemental application fee equal to the difference in the increase in capital costs from the original application as filed and the accepted modification based on one quarter of one percent (0.25%) of the revised capital expenditure costs.

(e) Any change order request submitted in accordance with ~~section~~ §15.0 ~~herein~~ of these Regulations that proposes to increase the total approved capital cost of a proposal shall include a supplemental application fee equal to the difference between capital costs as originally approved and the amount of increase in capital cost requested. The amount of the supplemental fee shall be based on one quarter of one percent (0.25%) of the proposed capital expenditure increase.

Reports, Use of Experts, All Costs and Expenses

(f) The state agency may in effectuating the purposes of ~~Chapter 23-15 of the Rhode Island General, as amended,~~ the Act engage experts or consultants including, but not limited to, actuaries, investment bankers, accountants, attorneys, or industry analysts. Except for privileged or confidential communications between the state agency and engaged attorneys, all copies of final reports prepared by experts and consultants, and all costs and expenses associated with the reports, shall be public. All costs and expenses incurred under this provision shall be the responsibility of the applicant in an amount to be determined by the Director as he or she shall deem appropriate. No application made pursuant to the requirements of ~~Chapter 23-15 of the Rhode Island General, as amended,~~ the Act shall be considered complete unless an agreement has been executed with the Director for the payment of all costs and expenses in accordance with this section. The maximum cost and expense to an applicant for experts and/or consultants that may be required by the state agency shall be twenty thousand dollars ($20,000)~~; provided however, that the maximum amount shall be increased by regulations promulgated by the state agency on or after January 1, 2008 by the most recently available annual increase in the federal consumer price index as determined by the state agency~~.

4.2 A duplicate copy of each application together with all supporting documentation shall be kept on file ~~in~~ by the state agency as a public record.

4.3 A formal application shall contain the following information, as a minimum, regarding any new institutional health service or new health care equipment:

(a) A brief description of the project setting forth the proposed new institutional health service or new health care equipment;

(b) The nature of the additional health care services to be provided as a result of the proposed new institutional health service or new health care equipment including a description of proposed programs for service linkages with other health care facilities

and programs for achieving continuity of patient care;

(c) The proposed location of the new institutional health service and/or new health care equipment together with acceptable schematic plans consisting of single line drawings (if applicable);

(d) Demonstration of a public need for the proposed new institutional health service or new health care equipment and for the scope thereof at the time and place and under the circumstances proposed, considering the availability of existing facilities, equipment and services, both statewide and on a local basis, which may serve as alternatives or substitutes for the whole or any part of the proposed new institutional health service or new health care equipment.

In demonstrating public need, the applicant shall, as a minimum, perform the following:

(1) Demonstrate the current service and target population involved and where appropriate, the projected population changes;

(2) Delineate the health needs of the above populations;

(3) Inventory the facilities or services currently available or proposed capable of meeting the types of health needs identified in §4.3(d)(2) of these Regulations ~~above~~;

(4) Determine that portion of need which is not satisfied;

(5) Identify and evaluate alternative proposals to satisfy the unmet need; and

(6) Delineate the justification for the specific alternative proposed, including the scope thereof.

(e) In the case of an application from an existing facility, an identification of any outstanding health care facility licensure deficiencies, citations or accreditation problems as may have been cited by the appropriate authority. In the case of proposed new health care facilities, a description of the quality assurance programs and/or activities which will relate to the application including both inter- and intra-facility programs and/or activities and outcome analysis whether mandated by the state or federal governments or voluntarily assumed. In the absence of such programs and/or activities, the applicant shall provide a full explanation of the reasons for such absence;

(f) An analysis of the cost of the proposed new institutional health service or new health care equipment including all design fees and related expenses as enumerated in ~~section 3.18~~ §§ 3.19(b)(1) and (2) ~~herein~~ of these Regulations together with the relationship of such cost to the total value of the facility's physical plant, equipment, and health care services for both capital and operating costs. Such analysis shall include a reasonable forecast for inflation for the expected time period that is proposed to elapse between the submission of the application and the ultimate implementation date of the proposal;

(g) A financial plan for operating and capital expenses and income for the period immediately prior to, during, and for three (3) years after complete implementation of the new institutional health service or new health care equipment;

(h) A statement of the sources of funds for the new institutional health service or new health equipment showing funds derived from the applicant's own sources and from borrowing, and further showing:

(1) Evidence of equity commitment;

(2) Interest rate for the proposed debt financing;

(3) Term for the proposed debt financing;

(4) Principal amount borrowed;

(5) Points, discounts, or origination fees, etc;

(6) A debt service schedule with annual outlays for principal and interest on the amount borrowed;

(7) Evidence that alternative methods of financing have been investigated;

(8) A comparison of the proposed method of financing with financing through a tax-exempt bonding authority;

(9) An annual analysis of cash flow for the period between approval of the application and the third full year of operation of the new institutional health service or new health care equipment;

(10) A depreciation schedule for the new institutional health service or new health care equipment showing useful life, method of depreciation, and salvage value;

(11) Audited financial statements for the most recent year available;

(12) Where refinancing of existing debt is contemplated, the original principal, current balance or principal, interest rates, term remaining, and documented justification for the refinancing contemplated;

(13) With respect to a proposed lease, a comparison of the lease with the option of purchase, showing term of lease, annual lease payments, salvage value of equipment at lease termination, purchase options, value of insurance and service options contained in the lease, discounted cash flows under both lease and purchase arrangements, and discount rate;

(14) Such financial indicators as may be requested by the state agency.

(i) Evidence of site control - a fee simple or such other estate or interest in the site including necessary easements and rights of way, sufficient to assure use and possession for the purpose of the construction and operation of the facility (applicable only to new institutional health services involving new construction, a new premise, or a new licensed health care facility);

(j) Evidence of the receipt from the applicable zoning authority of an application for zoning approval where such zoning approval is required by the municipality in which the facility is to be located (applicable only to new institutional health services involving new construction, renovations, new premises, or a new licensed health care facility). Failure to obtain needed zoning approval(s) within the time period allowed for project implementation as set forth in ~~section~~ §14.1(g) or such time period for implementation as otherwise specifically set by the state agency in its decision shall be grounds for the withdrawal of any approval of any certificate of need granted subject to any zoning approvals;

(k) Evidence from the appropriate state and/or municipal authority(ies) of an approved plan

for water supply and sewage disposal (applicable to new institutional health services involving new construction or the expansion of patient occupancy);

(l) Assurance of and/or evidence of compliance with other federal, state, or municipal fire, safety, use or occupancy or other health facility licensure requirements;

(m) A projected manpower budget specifying the personnel required for the staffing of the proposed new institutional health services or new health care equipment and the contemplated program and plan for the recruitment and training of personnel (if applicable);

(n) The estimated date of contract award (if applicable);

(o) A statement of the arrangements for architectural services that have been made or are anticipated including the name of the architect (if applicable);

(p) Evidence that the applicant has adequately planned for any temporary move or relocation of any facility or service which may be necessary during any proposed construction period, and evidence that the applicant has planned adequately to assure patient protection from noise, dust, etc. and to the extent possible, continuation of services during any proposed construction period (applicable only to new institutional health services involving construction or renovation);

(q) A statement of the period of time estimated to be required for the completion of construction or implementation of a change in service after approval of the formal application;

(r) An analysis and description of the impact of the proposed new institutional health service or new health care equipment, if approved, on the charges and anticipated reimbursements in any and all affected areas of the facility including consideration of such impacts on individual units of service and on an aggregate basis by individual class of payer.

(s) From the applicant's perspective, comments on the affordability of the proposed new institutional health service or new health care equipment and of the scope thereof at the time and place and under the circumstances proposed considering the affordability of the proposal as defined in ~~3.4 above~~ §3.5 of these Regulations, as applicable.

(t) In the case of an application involving the establishment of a new health care facility, evidence must be provided that the applicant has legally incorporated said entity in accordance with the requirements of the General Laws of Rhode Island, or in the absence of such evidence, the applicant must provide written documentation attesting to the facts of the legal status of the proposed entity. The application shall provide full disclosure of all entities, subsidiaries, or persons within a legal chain of control which shall include, but is not limited to ownership type, the names, addresses, and principal occupations of all owners or holders of equity interest in the entity, proposed or established by-laws, and such other relevant related information as may be deemed necessary by the state agency for full disclosure.

(u) In each application, the chief executive officer, the chairperson of the governing board, or other such person equating to the owner or person in charge of the applicant shall certify as to the completeness, accuracy, and veracity of the contents of the application;

and

(v) Any additional information pertaining to the new institutional health service or new health care equipment which the state agency may deem necessary for analysis of the applicable considerations outlined in ~~section~~ §9.12 ~~herein~~ of these Regulations.

4.4 Acceptance of the application "in form" by the state agency at the time of submission shall in no way be construed as indicating that additional information may not later be required and shall not be construed as having any effect on the merits of the application or of the contents thereof.

4.5 Notwithstanding the preceding application requirements or other certificate of need requirements contained ~~herein~~ in these Regulations, the state agency may periodically issue requests for proposals for the purpose of soliciting specific and limited certificate of need proposals from prospective applicants to address a potential need for development or expansion of a particular health care service or health equipment. The state agency shall prepare and publish the specifications for each request for proposal which shall include the following requirements:

(a) The specific subject matter for development or expansion;

(b) The selection criteria to be utilized;

(c) The time frames for submission and project implementation;

(d) Relevant cost and affordability considerations;

(e) Selection process; and

(f) Other pertinent review considerations and administrative procedures.

Section 5.0 **[REMOVED]** ~~***Acquisition of Health Care Facilities***~~

~~5.1 Capital expenditures made to acquire a health care facility are reviewable in accordance with 3.19(b), if such capital expenditure will result in a change in the services or bed capacity to be offered by such facility.~~

~~5.2 In order to determine whether a health care facility must file an application for approval of the capital expenditure, at least thirty (30) days before any person acquires or enters into a contract to acquire an existing health care facility, the person shall make written notification to the state agency of the person's intent to acquire the facility and of the services to be offered in the facility and its bed capacity.~~

~~5.3 The state agency will respond to the notice of intent within fifteen (15) working days with a determination as to whether an application for approval of the capital expenditure must be filed with the state agency.~~

~~5.4 If the state agency determines that an application is not required and a person acquires an existing health care facility without a certificate of need but proposes to change the services or bed capacity of the facility within one (1) year after the acquisition, the proposed change must be reviewed if it would have required review under section 3.18 herein originally.~~

~~5.5 In instances of the acquisition of health care facilities where there will be no changes in services provided or in bed capacity or designations which would require certificate of need review and approval prior to implementation, the filing of an application for change in ownership under the provisions of Chapter 23-17 of the Rhode Island General Laws, as amended, shall serve as notice of intent to acquire a health care facility.~~

Section 6.0 ***Review of Non-Clinical Capital Expenditures***

6.1 Capital expenditures by a health care facility that are not directly related to the provision of health services as defined in ~~this Chapter~~ the Act, including but not limited to capital expenditures for parking lots, information systems, telephone systems shall not require a certificate of need review and approval by the state agency.

Section 7.0 ***Review of Research Proposals***

7.1 Capital expenditures by a health care facility related to research in basic biomedical or medical research areas that are not directly related to the provision of clinical or patient care services shall not require a certificate of need review and approval ~~by the state~~ pursuant to these Regulations.

Section 8.0 ***Review of Voter Approval Capital Bond Issues***

8.1 Voter approved state bond issues authorizing capital expenditures for health care facilities shall not require a certificate of need review and approval by the state agency.

Section 9.0 ***Review Procedures***

9.1 Proposals for new institutional health services and new health care equipment shall be subdivided into three (3) categories for purposes of review:

(a) Expeditious review;

(b) Accelerated review; and

(c) Regular review.

9.2 Applicants shall file a detailed letter of intent on a form provided by the state agency at least forty-five (45) days prior to the submission of a certificate of need application.

9.3 Applicants must file three (3) copies of the completed application at the time of initial submission. Any application filed with the state agency must include an application fee. The application fee shall be considered to be a necessary part of the initial submission and failure to abide by this application fee requirement shall preclude any further consideration of the application and review will be initiated. ~~Once the state agency has determined that the original filing is acceptable in form (or that an amended filing is acceptable in form) a total of twenty-five (25) copies of the acceptable application materials shall be provided at least seven (7) days prior to the initiation date of the review.~~

(a) Any application for expeditious review~~s~~ may be submitted at any time. ~~If it is~~

~~determined that an expeditious review is not appropriate, the application shall be held for review until the applicable succeeding regular review cycle.~~

(b) Any application for accelerated review ~~requests~~ shall be submitted on or before the date of the appropriate regular review cycle of 10 January or 10 June.

(c) Any application for a regular review must be received at the Office of Health Systems Development by 4:30 P.M. on 10 January or 10 June.

(d) Any application ~~Applications other than expeditious reviews~~ received after the stipulated dates for review shall ~~be held for review until the subsequent applicable cycle~~ not be processed in that current review cycle.

9.4 For purposes of each review cycle category, each application received shall be batched with all other applications simultaneously under review. Further, each application may be grouped with similar applications based upon the type of health care facility involved, identity of the geographical area, service population, or the nature of the proposal to insure the full benefits of comparison for competing applications and to evaluate the impact on affordability of those proposals.

9.5 **[REMOVED]** ~~Except in the cases of expeditious reviews, or accelerated reviews, the procedures outlined in section 9.6 through 9.12 shall be employed for the conduct of reviews of new institutional health services and new health care equipment.~~

9.6 (a) The state agency, ~~on~~ by 10 July and 10 February shall give written notification to affected persons and/or others requested by the applicants, or the state agency, of the beginning of the review cycle. Such notice shall include the following specific facts:

(1) A description of the subject matter of the applications filed and of the principal issues involved;

(2) The proposed schedule for the review;

(3) The period within which a public meeting may be held, if requested by an affected person~~, not to exceed forty-five (45) days from the date of notification of affected persons~~;

(4) The manner by which notification will be provided, of the time and place of the public meeting, should one be requested;

(5) The manner by which written comment may be provided to the state agency; and

(6) If deemed appropriate by the state agency, whether accelerated review will be provided.

(b) Failure of ~~an~~ any affected person to receive written notification in accordance with this section shall not be grounds for reversal of a decision of the state agency or defeat the jurisdiction thereof or affect adversely the regularity of any proceedings before same.

(c) "Notification" is the date on which the notice is sent to applicants and to affected persons.

9.7 If an application is deemed not acceptable in form after initial staff review, the applicant shall be informed of the reasons for its rejection within ten (10) working days of its receipt. The applicant may then submit the materials required by the state agency to correct the deficiencies cited as forming the basis for rejection, provided such submission can be made at least seven (7) days prior to the date for initiation of the review cycle. Such submissions shall be considered to form part of the original application filed by the applicant.~~ Any submissions filed after the stipulated date shall be ineligible for review until the applicable subsequent cycle.~~

9.8 Acceptance of an application in form shall not be construed as affecting the sufficiency of the information provided in substance. The burden of proof is upon the applicant to prove the public need and affordability for the specific new institutional health service or new health care equipment proposed to be offered or developed, and the scope thereof, and to demonstrate compliance with all matters required by law and these Regulations ~~herein~~, through the information provided in the application.

9.9 If, during the conduct of a review, new information provided by the applicant subsequent to the filing of its formal application is contradictory to the information provided in the formal application or if such new information suggests the proposal contemplated by the applicant to be materially different from that presented in the original application, the Director of Health may terminate the review. The applicant may resubmit the proposal in an applicable subsequent review cycle.

9.10 Affected persons, including those parties defined in section 3.3 §3.4 and the state Department of Business Regulation, the Department of Mental Health, Retardation and Hospitals, the Department of Human Services, the state peer review organization, affected cities and towns, and such other agencies and/or persons as may be deemed appropriate in the context of an individual application, shall be afforded an opportunity to provide written comment with respect to each application submitted. Any comment so initiated must be received by the state agency within fifty (50) days, when practicable, from the date of notification of affected persons except in the case of:

(a) Expeditious reviews or accelerated reviews when comments must be received within twenty (20) days, when practicable, of the date of notification of affected persons, or

(b) Public meetings shall be held in accordance with ~~section~~ §10.0.

9.11 The time frame for review shall be as follows:

(a) The decision of the state agency may be rendered within one hundred twenty (120) days of the date of notification of affected persons. The maximum period of review by the Health Services Council shall not exceed one hundred fifteen (115) days and that the state agency decision shall be rendered within five (5) days of the Health Services Council's determination of its recommendation.

(b) If the state agency fails to act upon an application within one hundred twenty (120) days, the applicant may apply to the superior court of Providence County to require the state agency to act upon the application.

9.12 The Health Services Council shall analyze, as deemed appropriate, no less than the following considerations in conducting reviews:

(a) The relationship of the proposal to such state health plans as may be formulated by the state agency;

(b) The impact of approval or denial of the proposal on the future viability of the applicant and of the providers of health services to a significant proportion of the population served or proposed to be served by the applicant;

(c) The need that the population to be served by the proposed equipment or services has for the specific new institutional health service or new health care equipment and the scope thereof; and the extent to which such proposed services or equipment will be accessible to residents of the state, particularly those traditionally underserved;

(d) The availability of alternative, less costly, or more effective methods of providing such services or equipment, including economies or improvements in service that could be derived from feasible cooperative or shared services;

(e) The availability of funds for capital and operating needs for the provision of the services or equipment proposed to be offered;

(f) The effect of the means proposed for the delivery of such services on the clinical needs of health professional training programs in the state;

(g) If such services are to be available in a limited number of facilities, the extent to which the health profession schools in the area will have access to the services for training purposes;

(h) The immediate and long term financial feasibility of the proposal including:

(1) The reasonableness of utilization projections,

(2) The probable impact of the proposal on the reimbursement system, on the cost of and charges for health services of the applicant and on the cost of health care in the state,

(3) The relative availability of funds for capital and operating needs for the provision of the services or equipment proposed to be offered,

(4) The cost of financing the proposal including the reasonableness of the interest rate, the period of borrowing and the equity position of the applicant.

(i) The impact of the proposal on the quality of health care in the state and in the population area to be served by the applicant;

(j) In the case of existing services or facilities, the quality of care provided by those facilities in the past;

(k) The efficacy of the proposed new institutional health service or new health care equipment;

(l) The relationship, including the organizational relationship of the services or equipment proposed, to ancillary or support services and to the existing health care system of the state;

(m) Special needs and circumstances of those entities which provide a substantial portion of

their services or resources, or both, to individuals not residing within the state;

(n) Special needs of such entities as medical and other health professional schools, multi-disciplinary clinics and specialty centers;

(o) The special needs for and availability of osteopathic facilities and services within the state, including the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship and residency levels;

(p) In the case of a construction project:

(1) The costs and methods of the proposed construction, and projected life cycle operating costs;

(2) The probable impact of the construction project reviewed on the costs of providing health services by the person proposing such construction project and on the costs and charges to the public of providing health services by other persons;

(3) The proposed availability and use of safe patient handling equipment in the new or renovated space to be constructed.

(q) The factors which affect the effect of competition on the supply of the health services being reviewed with particular emphasis on the prevailing method of paying for inpatient health services by public and private health insurers;

(r) Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness, particularly as such relate to the prevailing method of paying for inpatient health services and other institutional health services by public and private health insurers;

(s) The efficiency and appropriateness of the use of existing services and facilities similar to those proposed, including the extent to which the proposed new service or equipment, if implemented, will not result in any unnecessary duplication of existing services and equipment.

(t) In the case of review of proposals by health care facilities who by contractual agreement, ~~Chapter 19 of Title~~ RIGL Chapter 27-19 or other statute are required to adhere to an annual schedule of budget or reimbursement determination to which the state is a party, the State Budget Office, the Office of the Health Insurance Commissioner, and Hospital Service Corporations organized under ~~Chapter 19 of Title 27~~ RIGL Chapter 27-19 shall forward to the Health Services Council within forty-five (45) days of the initiation of the review of the proposals by the Health Services Council under ~~section~~ §23-15-4(f)(1) of the Act ~~General Laws of Rhode Island, 1956, as amended~~:

(i) A cost impact analysis of each proposal which analysis shall include but not be limited to consideration of increases in operating expenses, per diem rates, health care insurance premiums and public expenditures; and

(ii) Comments on acceptable interest rates and minimum equity contributions and/or maximum debt to be incurred in financing needed proposals.

(u) The ability of the people of the state to afford the proposal as defined in section 3.4 ~~herein~~ §3.5 of these Regulations including consideration of the condition of the state's economy, the statements of authorities and/or parties affected by such proposals, and

economic, financial, and/or budgetary constraints affected by such proposals including such written cost impact analysis as may be provided by the State Medicaid Agency, State Budget Officer or other affected parties.

(v) The potential of the proposal to demonstrate or provide one (1) or more innovative approaches or methods for attaining a more cost effective and/or efficient health care system;

(w) The relationship of the proposal to the potential need indicated in any requests for proposals issued by the state agency in accordance with the requirements of ~~section~~ §4.5 ~~herein~~ of these Regulations;

(x) Cost impact statements forwarded pursuant to ~~section~~ §23-15-6(e) of the Act ~~Rhode Island General Laws, as amended~~;

(y) The input of the community to be served by the proposed equipment and services and the people of the neighborhoods close to the health care facility who are impacted by the proposal;

(z) The relationship of the proposal to any long-range capital improvement plan of the health care facility applicant; and

(aa) Any other factors deemed relevant by the Health Services Council or the Director.

Section 10.0 ***Public Meetings***

10.1 If requested in writing by an affected person, as defined in ~~section 3.3 herein~~ §3.4 of these Regulations, a public meeting may be held during the course of the state agency review at which any person may have the opportunity to present testimony.

10.2 The request must be received by the state agency within fifteen (15) days of the date of written notification to affected persons of the beginning of a review, provided in accordance with ~~section~~ §9.6 ~~herein~~ of these Regulations.

10.3 The following rules of procedure shall apply to the conduct of public meetings:

(a) Notification of the date, time, location and subject matter of the public meeting shall be provided to affected persons. Failure of an affected person to receive notification in accordance with this section shall not be grounds for reversal of a decision of the state agency or defeat the jurisdiction thereof or affect adversely the regularity of any proceedings before same.

(b) The public meeting shall be conducted by the Health Services Council.

(c) Any affected person shall have the right to present testimony.

Section 11.0 ***Expeditious Review***

11.1 Any person who proposes to offer or develop new institutional health services or new health care equipment may request an expeditious review:

(a) For emergency needs documented in writing by the state fire marshal or other lawful

authority with similar jurisdiction over the relevant subject matter;

(b) For the purpose of eliminating or preventing fire and/or safety hazards certified by the state fire marshal or other lawful authority with similar jurisdiction of the relevant subject matter as adversely affecting the lives and health of patients or staff;

(c) For compliance with accreditation standards failure to comply with which will jeopardize receipt of federal or state reimbursement;

(d) For such an immediate and documented public health urgency as may be determined to exist by the Director of Health with the advice of the Health Services Council. The Health Services Council shall not be deemed to have recommended expeditious review under this criterion except by a two thirds affirmative vote of the members present at the time of the vote.

11.2 The state agency shall exercise its discretion in granting an expeditious review and may waive the public meeting provision during the course of review.

11.3 Affected persons other than the Health Services Council shall be provided no more than twenty (20) days for review and comment to the state agency in the case of an expeditious review.

11.4 In the case of an expeditious review submitted by a health care facility required by contractual agreement, RIGL Chapter 27-19, or other statute to adhere to an annual schedule of budget determination to which the state is a party, the state budget office and hospital service corporations organized under RIGL Chapter 27-19 ~~of the General Laws of Rhode Island, 1956, as amended~~, shall provide the state agency with a cost impact analysis for the proposal.

11.5 The decision of the state agency not to conduct an expeditious review is not subject to reconsideration or administrative review; provided, however, affected parties shall be afforded, with respect to any decision on the merits rendered by the state agency through the mechanism of an expeditious review, all rights of administrative review delineated in ~~section~~ §§23-15-6(b)(9) and (10) of the Act ~~Rhode Island General Laws, as amended~~, as further elucidated in ~~section~~ §§17.0 through 18.0 ~~herein~~ of these Regulations.

11.6 The decision of the state agency in an expeditious review shall be rendered within forty-five (45) days of the initiation of said review, when practicable.

Section 12.0 ***Accelerated Review***

12.1 (a) Accelerated review may be requested by applicants on or before the date of the regular review cycle of 10 January or 10 July. In order to qualify for proposed processing under accelerated review, the state agency must identify and preliminarily determine that there is a prima facie demonstration of public need and affordability for the proposal. This identification and preliminary determination shall be made before the date scheduled for the initiation of Health Services Council review.

(b) The state agency shall exercise its discretion, in accordance with the criteria set forth in

(a) above, in proposing accelerated review. For those proposals for which the state agency proposes accelerated review, the state agency shall:

(1) Make a written preliminary finding that the proposal presents a prima facie demonstration of public need and affordability consistent with the criteria set forth above, and

(2) Make written preliminary findings consistent with the criteria set forth in ~~section~~ §§13.3 and 13.4 ~~herein~~ of these Regulations.

(c) The initiation of review notice provided to affected parties and to the public shall clearly indicate the state agency's intention to propose accelerated review. The public comment period for such reviews may be limited to twenty (20) days. The state agency may propose a preliminary report on such application provided such proposed report meets all the requirements of ~~section~~ §§13.3 and 13.4 ~~herein~~ of these Regulations regarding required findings and review considerations. The Health Services Council may consider such proposed report and may provide its advisory to the Director of Health by adopting such report in amended or unamended form. The Health Services Council, however, is not bound to accept such report nor is it bound to recommend to the Director that the proposal be processed under the accelerated review mechanism.

(d) Written objections from affected persons directed to the processing under the accelerated review mechanism and/or the merits of the proposal shall be accepted during a ~~20 (twenty)~~ twenty (20) day comment period which shall begin at the initiation of review. Objections to going forward with an accelerated review (as distinct from objections directed to the merits of the proposal) shall give clear, substantial, and unequivocal rationale as to why the proposal ought not to be processed under the accelerated review mechanism. The Health Services Council shall take under advisement all objections both as to the merits and as to proceeding with an abbreviated review and shall make a recommendation to the Director with respect to each. Should the Health Services Council not recommend to the Director that the proposal be processed under the accelerated review as initially proposed, such application may be processed consistent with the time frames and procedures for proposals not recommended for accelerated review and may be batched with those reviews which were contemporaneously initiated. If accelerated review is not granted, then the comment period may be forthwith extended consistent with the time frames in ~~section~~ §9.10 ~~herein~~ of these Regulations for proposals not under accelerated review or expeditious review. The Director, with the advice of the Health Services Council, shall make the final decision either to grant or to deny an accelerated review and shall make the final decision to grant or to deny the proposal on the merits within the accelerated review mechanism and time frames.

(e) If applicable, the state budget office and hospital service corporations organized under RIGL Chapter 27-19 ~~of the General Laws of Rhode Island, 1956, as amended,~~ shall provide the state agency with a cost impact analysis for the proposal.

Section 13.0 ***Findings and Recommendations***

13.1 At the conclusion of its review of each application for new institutional health services or new health care equipment, the Health Services Council shall make recommendations to the

state agency relative to approval or denial of the new institutional health services or new health care equipment proposed.

13.2 Such recommendations shall explicitly address the information required in accordance with ~~section~~ §4.3 ~~herein~~ of these Regulations and the relevant considerations outlined in ~~section~~ §9.12 ~~above~~ of these Regulations. Such findings and recommendations shall take into consideration policies adopted publicly by the state agency, and any apparent or real differences shall be illustrated as to the factors of consideration involved.

13.3 The findings of the Health Services Council shall include commentary where applicable, on the following elements derivable from the information provided in accordance with ~~section~~ §4.3 of these Regulations ~~herein~~:

(a) The relationship of the proposal to such state health plans as may be formulated by the state agency;

(b) The applicant's demonstration of public need for the specific proposal and the scope thereof;

(c) A detailed analysis of all elements (capital and operating) of the total project cost including prospective sources of payment for associated operating expenses;

(d) The incremental cost to the health care system of provision of the additional services and the consequent impact of the proposal upon the overall costs of the institution, upon patient charges, and upon the reimbursement system;

(e) The feasibility of the proposal including the mix of financing and the reasons therefore as they relate to the overall financial structure of the applicant and such other factors as may impinge upon the feasibility of the proposal;

(f) The derivable operating efficiencies (i.e., economies of scale or substitution of capital for personnel) which may result in lower total or unit costs;

(g) The efficiency and appropriateness of the use of existing inpatient facilities providing inpatient services similar to those proposed (if applicable);

(h) The efficiency and appropriateness of the proposed new institutional health services, including the extent to which the proposed new service or equipment, if implemented, will not result in any unnecessary duplication of existing services or equipment;

(i) The affordability of the proposal; and

(j) For proposals subject to ~~Chapter~~ §23-15-6(e) of the Act, the relative priority of the proposal compared to all other proposals simultaneously under review.

13.4 The Health Services Council shall not make a recommendation to the state agency that a proposal be approved unless it is found that the proposal is affordable to the people of the state. In determining whether or not a proposal is affordable, the Health Services Council shall consider the condition of the state's economy, the statements of authorities and/or parties affected by the proposals, and such other factors as it may deem appropriate.

13.5 In addition, the following written findings shall be made prior to the approval of any proposal for provision of additional inpatient services:

(a) That superior alternatives to such inpatient services in terms of cost, efficiency and appropriateness do not exist and that the development of such alternatives is not practicable;

(b) That, in the case of new construction, alternatives to new construction such as modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable;

(c) That patients will experience serious problems in terms of cost, availability, or accessibility in obtaining inpatient care of the type proposed in the absence of the proposed new service; and

(d) That, in the case of a proposal for addition of beds for the provision of nursing facilities the relationship of the addition to the plans of the agencies of the state responsible for providing and financing long term care has been considered.

13.6 The state agency shall make written findings (taking into account the accessibility of the health care facility as a whole) on the extent to which the proposal, if approved, will meet the following accessibility criteria:

(a) The extent to which low income persons, racial and ethnic minorities, women, handicapped persons, and the elderly presently have access to such services and the extent to which such groups are likely to have access to this service;

(b) In the case of a reduction, elimination or relocation of a service, the need that the population presently served has for the service, the extent to which that need will be adequately met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of the groups noted in ~~section (a) above~~ §13.6(a) of these Regulations to obtain needed health care;

(c) The performance of the applicant regarding its provision of uncompensated care, community services or access by minorities and handicapped persons to programs receiving federal financial assistance, including the existence of any civil rights access complaints against the applicant;

(d) The extent to which Title XVIII (Medicare), Title XIX (Medicaid) and medically indigent patients are served by the applicant;

(e) The extent to which the applicant offers a range of means by which a person will have access to its services (e.g., outpatient services, admission by house staff, admission by personal physician);

(f) The extent to which the applicant grants medical staff privileges to physicians who serve the indigent; and

(g) The extent to which the applicant takes actions necessary to remove barriers that limit access to the health services of the applicant (e.g., transportation, language, facility design and financial barriers).

13.7 The state agency shall render a written decision (which shall be the final decision for the purpose of determining the applicable time frame in accordance with ~~section~~ §23-15-6(b)(2) of the Act ~~Rhode Island General Laws, as amended~~) on all applications for new health care

equipment or new institutional health services based on the findings and recommendations of the Health Services Council unless the state agency shall afford written justification for variance therefrom. In the case of approvals of new health care equipment or new institutional health services for the provision of health services to inpatients, the state agency's decision shall include the written findings required in accordance with ~~section~~ §23-15-6(b)(6)(i) of the Act ~~General Laws of Rhode Island, 1956, as amended~~. The provisions of ~~section~~ §13.2 ~~herein~~ of these Regulations shall have applicability to the formulation of the written decisions of the state agency.

13.8 If the state agency renders a decision contrary to the findings and recommendations of the Health Services Council, it must afford written justification for its variance therefrom.

13.9 In rendering its decision, the state agency may approve or disapprove, in whole or in part, any application as submitted.

13.10 Each decision of the state agency to issue or not to issue a certificate of need must be based on the review by the state agency conducted in accordance with the procedures and criteria adopted under these Regulations ~~herein~~ and on the record of the administrative proceedings held on the application for the certificate or the state agency's proposal to withdraw the certificate.

13.11 In any case where the state agency finds that an approved project does not satisfy the criteria in ~~section 13.5~~ §13.6 of these Regulations, it may, if it approves the application, impose the condition that the applicant take affirmative steps to meet those criteria.

Section 14.0 ***Conditions of Approval***

14.1 All approvals granted by the state agency are subject to the following conditions:

(a) That the applicant must complete the approved construction at a total cost not to exceed that stipulated in the decision of the state agency;

(b) That the applicant will cause the project to be completed in accordance with the application as approved;

(c) That any changes to the application as approved must be submitted to the state agency for prior authorization;

(d) That the state agency must be apprised of the award of any contract associated with the proposed new institutional health service or new health care equipment and must be provided with a copy of the bid award and/or guaranteed maximum price (GMP) certifying the total bid price and stipulating any and all costs associated with the proposal, within a reasonable period of time as determined administratively by the state agency;

(e) That any change orders to the contract as awarded or increase in the contract price must be submitted to the state agency for information, except that change orders or other cost increases which exceed the contingency reserve for a project must be submitted to the state agency for prior authorization in accordance with ~~section~~ §15.0 ~~herein~~ of these Regulations;

(f) That the state agency may withdraw approval of any new institutional health service or new health care equipment, not involving construction, if the applicant fails to initiate development of such new institutional health service or new health care equipment within one (1) year (or other time period for implementation as specifically required in the state agency decision) of the date of such approval;

(g) That the state agency may cancel or withdraw approval of a new institutional health service involving construction if the applicant fails:

(1) To execute a contract to initiate such construction within one (1) year of the date of approval of the application (or other time period for implementation as specifically required in the state agency decision) and;

(2) To demonstrate sufficient progress towards project completion as documented in the summary progress report required by ~~section~~ §14.1(h) ~~herein~~ of these Regulations;

(h) That, if specifically requested in writing by the state agency, a summary progress report, detailing costs incurred, shall be filed with the state agency at six (6) month intervals from the date of final state agency decision until full implementation of the approved new institutional health service or new health care equipment;

(i) That in the case of a proposed new institutional health service involving new construction, the Director of Health or his/her authorized representative may at any time during the course of construction or upon the completion of the project make an on-site inspection of the construction and equipment to check for compliance of the construction in accordance with the terms of his/her prior approval;

(j) That the facility shall comply with the building laws, codes and regulations of the municipality where such facility is located, applicable laws, codes and regulations of the state of Rhode Island, and applicable federal codes and standards unless a variance therefrom shall have been allowed by the appropriate agency;

(k) That the state agency must be provided with documentation of the final financing arrangements (including total amount funded, equity funds and source, borrowed funds and source, term of loan, interest rate, schedule for retirement of debt, and terms of interim borrowing, if any) associated with the provision of the approved new institutional health service or new health care equipment within thirty (30) days of the establishment of said arrangements;

(l) That failure to obtain needed zoning approval(s) on a timely basis consistent with the requirements of ~~section~~ §15.0 shall be grounds for the withdrawal of any certificate of need granted subject to any zoning approval(s); and

(m) Any other condition deemed appropriate by the state agency provided such condition directly relates to the considerations outlined in ~~section~~ §9.12 ~~herein~~ of these Regulations.

14.2 Acceptance of the state agency's decision by the applicant includes acceptance of all conditions attached thereto.

14.3 The decision of the state agency, including its findings and recommendations, shall be distributed to the applicant and upon written request to others.

14.4 At least annually, a report of reviews conducted, together with the findings and decisions rendered in the course of such reviews, shall be published by the state agency.

14.5 Applications reviewed by the agency and all written materials pertinent to agency review, including minutes of all Health Services Council meetings, shall be accessible to the public.

14.6 In addition, upon written request filed in conformance with ~~section~~ §19.0 of the ~~amended~~ *Rules and Regulations of the 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*), the state agency shall make available, with respect to any review in process, information relative to the status of such review and, for any completed review, the findings of the state agency, with respect to such review, as well as any other information deemed appropriate.

Section 15.0 ***Changes, Cost Overruns, and Failure to Implement***

15.1 (a) Except for approved nursing facility proposals, any cost overrun that exceeds seven hundred and fifty thousand dollars ($750,000) or ten percent (10%) of the total approved capital cost, whichever is more, shall require review by the Health Services Council and approval of the state agency.

(b) For nursing facility proposals, any cost overrun that exceeds three hundred thousand dollars ($300,000) or ten percent (10%) of the total approved capital cost, whichever is less, requires review by the Health Services Council and approval of the state agency. ~~Cost overruns that are $300,000 or less shall be submitted to the state agency for administrative review and determination.~~

15.2 (a) All other changes (including changes in financing plans) to an approved project for provision of new institutional health services or new health care equipment shall require approval of the state agency.

(b) For the purpose of this section, a change includes any change in the bed capacity of a facility or the addition or termination of a health service which occurs within one (1) year after the date the activity for which the expenditure was approved is initiated or implemented, whether or not a capital expenditure is involved.

(c) If applicable, the state budget office and hospital service corporations organized under RIGL Chapter 17-19 ~~of the General Laws of Rhode Island, 1956, as amended,~~ shall provide the state agency with a cost impact analysis for the cost overrun.

15.3 Failure to initiate development of a new institutional health service or new health care equipment, not involving construction, within one (1) year of the date of approval of such new institutional health service or new health care equipment unless otherwise specifically conditioned in the state agency decision shall be grounds for review by the Health Services Council and the state agency to determine if approval should be withdrawn.

15.4 Failure to execute a contract to initiate construction of a new institutional health service within one (1) year of the date of approval of such new institutional health service unless otherwise specifically conditioned in the state agency decision shall be grounds for review

by the Health Services Council and the state agency to determine if approval should be withdrawn.

15.5 Failure to provide summary progress reports as required in ~~section~~ §14.1(h) ~~herein~~ of these Regulations shall be grounds for review by the Health Services Council and the state agency to determine if approval should be withdrawn.

15.6 Failure to demonstrate that sufficient progress is being made toward project completion as evidenced in the summary progress reports as required in ~~section~~ §14.1(h) ~~herein~~ of these Regulations shall be grounds for review by the Health Services Council and the state agency to determine if approval should be withdrawn.

15.7 Withdrawal of approval for failure to initiate development or to execute a construction contract in accordance with ~~section~~ §15.3 or §15.4 of these Regulations ~~above~~ shall preclude the applicant whose approval has been withdrawn from being considered as an existing or potential provider of the new institutional health service or new health care equipment for which approval was withdrawn, in the context of application by the Health Services Council of the considerations listed in ~~section 9.11 herein~~ §9.12 of these Regulations to pending or subsequent applications for similar services by other persons or health care facilities.

15.8 In conducting reviews in accordance with ~~sections~~ §§15.3 through 15.6 ~~herein~~ of these Regulations, the state agency shall provide written notification to the applicant and the Health Services Council stating the grounds, scope and procedures for initiating withdrawal of the certificate of need. Within thirty (30) days from the date of notification, the applicant shall provide written justification to the state agency for failure to implement or to demonstrate that sufficient progress is being made toward project completion in accordance with ~~section~~ §§15.3, 15.4, 15.5, and 15.6 ~~herein~~ of these Regulations. Upon receipt of this written justification or following the expiration of the allowed thirty (30) day period, the state agency shall forward said justification if furnished and other pertinent materials to the Health Services Council for review and recommendation. When practicable, the Health Services Council shall provide the state agency with a recommendation within forty-five (45) days of the receipt of the applicant's written justification if furnished regarding the failure to implement a project. The scope of the Health Services Council review and recommendation shall be limited to:

(1) The specific circumstances resulting in failure to implement or to make sufficient progress toward project completion; and

(2) The impact of this failure to implement or to make sufficient progress toward project completion on the public need for said services. Decisions by the state agency with respect to withdrawal of approval shall be rendered within fifteen (15) days of the completion of the Health Services Council's review.

15.9 The decision of the state agency rendered in accordance with this section is subject to the reconsideration and/or administrative review and/or judicial review outlined in ~~section~~ §§16.0 through 18.0 ~~herein~~ of these Regulations.

15.10 In the case of a decision by the state agency to disapprove any changes or cost overruns, sanctions available under ~~section~~ §23-15-4(h) of the Act ~~Rhode Island General Laws, as amended,~~ shall apply only to the costs associated with the changes and/or overruns disapproved thereby.

Section 16.0 ***Reconsideration***

16.1 (a) Any affected person may request in writing reconsideration of the state agency's decision if such person:

(1) Presents significant relevant information not previously considered by the state agency;

(2) Demonstrates that there have been significant changes in factors or circumstances relied upon by the agency in reaching its decision;

(3) Demonstrates that the agency has materially failed to follow its adopted procedures in reaching its decision; or

(4) Provides such other basis as the state agency determines constitutes good cause, which basis may be determined on a case-by-case basis.

(b) In determining what constitutes and what qualifies for presentation as "significant relevant information not previously considered by the state agency," the person must prove that said information was, is, or would be significant to the agency's final decision and was not previously available to the applicant for submission to the state agency during the period of the review process, provided, however, that nothing in this section shall be construed to permit or allow the reconsideration process to be used as a procedure for modification or amendment of an insufficient or deficient application or presentation during the review process or to introduce as new matter previously existing data as an alternative basis for approval of a project (e.g., fire code deficiencies to which no previous reference was made).

16.2 Requests for reconsideration of a state agency decision must be received within thirty (30) days of the decision.

16.3 If the state agency determines that good cause has been shown for reconsideration of its decision, a public meeting shall be scheduled within thirty (30) days of receipt of the request at which any person shall be afforded the opportunity to present testimony.

16.4 Notification of the public meeting shall be afforded to the person requesting the meeting, to the applicant (if different), to any person who has participated in the proceedings before the state agency provided said person has forwarded written comments which are part of the formal record before the state agency, and to other affected persons upon request at least seven (7) days prior to the proposed meeting date.

16.5 The reconsideration public meeting shall be conducted by ~~the adjudicative hearing officer of the state agency or his/her designee~~ a hearing officer appointed pursuant to §17.1 of these Regulations, who shall be empowered to stipulate time limitations on individual oral testimony when warranted by time constraints or the number of persons making oral

statements and who may use or apply the *Rules and Regulations of the 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*), where applicable, and where such rules are not inconsistent with ~~section~~ §16.1(b) of these Regulations ~~herein~~, provided however, that all written materials and data ~~submitted in writing~~ shall be submitted by the meeting date.

16.6 The ~~adjudicative hearing officer of the state agency or his/her designee~~ hearing officer appointed pursuant to §17.1 of these Regulations shall submit a written recommendation to the state agency, based upon the record and upon the testimony offered at the reconsideration public meeting.

16.7 The state agency shall make written findings which state the basis for its decision on the request for reconsideration within forty-five (45) days of the conclusion of the reconsideration public meeting.

16.8 The decision of the state agency rendered in accordance with ~~section~~ §16.7 ~~herein~~ of these Regulations is the final decision unless administratively reviewed in accordance with ~~section~~ §§17.0 and 18.0 ~~herein~~ of these Regulations.

Section 17.0 ***Administrative Review***

17.1 The decision of the state agency may be administratively reviewed at the written request of any affected person through an administrative review to be conducted by a hearing officer, hereinafter referred to as the administrative review agency, appointed by the Director of Health.

17.2 The written request for administrative review must be filed within thirty (30) days of the decision of the state agency (or, if applicable, within thirty (30) days after a reconsideration decision is made) and the administrative review must be initiated within thirty (30) days of the receipt of the request.

17.3 Within ten (10) days of the receipt of the request for an administrative review, the state agency shall give written notification to the applicant, the person who requested the review (if different), and by publication to any person who has participated in the proceeding before the state agency which notice shall include:

(a) A statement of the time, place, and nature of the administrative review;

(b) A statement of the legal authority and jurisdiction under which the administrative review is to be held;

(c) A reference to the particular sections of the statutes and rules involved; and

(d) A short and plain statement of the issues involved.

17.4 The burden of persuasion and of going forward shall be on the party seeking to set aside a decision of the state agency.

17.5 The grounds and scope of administrative review are limited to demonstrating that the substantial rights of the appellant have been prejudiced because the state agency findings, inferences, conclusions, or decisions are:

(a) In violation of constitutional or statutory provisions;

(b) In excess of the statutory authority of the agency;

(c) Made upon unlawful procedure;

(d) Affected by other error of law;

(e) Clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record; or

(f) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

17.6 The decision of the administrative review agency (as defined in ~~section~~ §17.1 ~~herein~~ of these Regulations) shall be based solely on the evidence introduced into the record before the state agency and facts officially noticed.

17.7 If, before the date set for administrative review, application is made to the administrative review agency for leave to present new significant relevant information not previously considered by the state agency, consistent with the limitations and criteria provided for in ~~section~~ §16.1(b) of these Regulations ~~herein~~, and it is clearly shown to the satisfaction of the administrative review agency that said new information is material and that there were good and substantial reasons for the failure to present it during the review before the state agency, the administrative review agency may order the matter remanded to the state agency upon conditions determined by the administrative review agency for the reception of said new information and decision by the state agency.

17.8 The administrative review agency, after the receipt of the request for administrative review from the state agency in accordance with §17.2 of these Regulations and the notice provided for in §17.3 of these Regulations shall conduct an appellate administrative review. The proceedings shall be transcribed at the request of the person filing the request for administrative review or at the request of the state agency. The administrative review agency may affirm the decision of the state agency or remand the case for further proceedings, or it may reverse or modify the decision if the substantial rights of the appellant have been prejudiced because the state agency's findings, inferences, conclusions or decisions are subject to reversal or modification because the same are violative of the criteria set forth in ~~section~~ §17.5 ~~herein~~ of these Regulations. The administrative review agency, in conducting its review, shall not substitute its judgment for that of the state agency as to the weight of the evidence on questions of fact.

17.9 Informal disposition may be made by stipulation, agreed settlement, consent order or default.

17.10 The record shall include:

(a) All pleadings, motions, and intermediate rulings;

(b) All evidence received or considered;

(c) A statement of matters officially noticed;

(d) Questions and offers of proof and rulings thereon;

(e) Proposed findings and exceptions, the findings to be based exclusively on the evidence and matters officially noticed;

(f) A written decision by the administrative review agency (as defined in ~~section~~ §17.1 ~~herein~~ of these Regulations) and by the officer presiding at the administrative review, pursuant to the jurisdiction of said officer, including findings of fact, (accompanied by a concise and explicit statement of the underlying facts supporting the findings) and conclusions of law, separately stated.

17.11 Ex-parte consultations shall be governed by the provisions of ~~section~~ RIGL §42-35-13 ~~of the Rhode Island General Laws, as amended~~.

17.12 The written decision of the administrative review agency shall be in accordance with the requirements of ~~section~~ RIGL §42-35-12 ~~of the Rhode Island General Laws, as amended~~, and shall be made within forty-five (45) days after the conclusion of the review, shall be distributed to the applicant and to the state agency and shall be available to others upon request.

17.13 The decision of the administrative review agency is the final decision unless judicial review is sought in accordance with ~~section~~ §18.0 ~~herein~~ of these Regulations.

Section 18.0 ***Judicial Review***

18.1 Any person adversely affected by a final decision of the state agency or administrative review agency may obtain judicial review of the decision in accordance with the provisions of ~~section~~ RIGL §§42-35-15 and 42-35-16 ~~of the Rhode Island General Laws, as amended~~, provided that the state agency shall be considered a "person."

Section 19.0 ***Sanctions***

19.1 The offering or developing of new institutional health services or health care equipment by a health care facility without prior review by the Health Services Council and approval by the state agency shall be grounds for imposition of licensure sanctions on such facility including denial, suspension, revocation or curtailment or for imposition of such monetary fines as may be statutorily permitted by virtue of individual health care facility licensing statutes.

19.2 No government agency and no hospital or medical service corporation organized under the laws of the state shall reimburse any health care facility or health care provider for the costs associated with offering or developing new institutional health services or new health care equipment unless the health care facility or health care provider has received approval of the state agency in accordance with the Act ~~Chapter 23-15 of the Rhode Island General Laws, as amended~~. Government agencies and hospital and medical service corporations organized under the laws of the state shall, during budget negotiations, hold health care facilities and health care providers accountable to operating efficiencies claimed or projected in proposals

which receive the approval of the state agency in accordance with the Act ~~Chapter 23-15 of the Rhode Island General Laws, as amended~~.

19.3 In addition, the state agency shall not make grants to, enter into contracts with, or recommend approval of the use of federal or state funds by any health care facility or health care provider which proceeds with the offering or developing of new institutional health service or new health care equipment after disapproval by the state agency.

Section 20.0 ***Severability***

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 applications of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

REFERENCES

1. *Rules and Regulations for the Licensing of Hospitals (R23-17-HOSP)*, Rhode Island Department of Health, ~~September 2007~~ April 2009 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4895.pdf~~
2. *Rules and Regulations for Licensing Rehabilitation Hospital Centers (R23-17-REHAB)*, Rhode Island Department of Health, September 2007 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4831.pdf~~
3. *Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers (R23-17-FASC)*, Rhode Island Department of Health, April 2005 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/DOH_3500.pdf~~
4. *Rules and Regulations for Licensing Hospice Care (R23-17-HPC)* , Rhode Island Department of Health, August 2007 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4726.pdf~~
5. *Rules and Regulations for Licensing of Nursing Facilities (R23-17-NF)*, Rhode Island Department of Health, October 2006 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/DOH_3498.pdf~~
6. *Rules and Regulations of the 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, May 2004 and subsequent amendments thereto. ~~Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/DOH_2945.pdf~~

The revision dates of all regulations cited above were current when these amended regulations were filed with the Secretary of State. Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: http://www.sos.ri.gov/rules/

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