

CHAPTER 33

CERTIFICATE OF NEED: APPLICATION AND REVIEW PROCESS

Authority

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

Source and Effective Date

R.2002 d.243, effective July 3, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 1246(a), 34 N.J.R. 2814(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 33, Certificate of Need: Application and Review Process, expires on December 30, 2007.
See: 39 N.J.R. 2709(a).

Chapter Historical Note

Chapter 33, Certificate of Need, was adopted as R.1972 d.93, effective on May 11, 1972. See: 4 N.J.R. 25(a), 4 N.J.R. 124(a). Chapter 33 was amended by R.1975 d.315, effective December 1, 1975. See: 7 N.J.R. 362(a), 7 N.J.R. 503(a); R.1979 d.283, effective July 20, 1979. See: 11 N.J.R. 174(a), 11 N.J.R. 439(a); R.1980 d. 36, effective January 17, 1980. See: 11 N.J.R. 620(a), 12 N.J.R. 75(e); R.1980 d.123, effective March 20, 1980. See: 12 N.J.R. 73(d), 12 N.J.R. 186(c); R.1981 d.296, effective August 6, 1981. See: 13 N.J.R. 267(a), 13 N.J.R. 487(b); and R.1983 d.205, effective June 6, 1983. See: 15 N.J.R. 307(b), 15 N.J.R. 920(c).

Pursuant to Executive Order No. 66(1978), Chapter 33 was readopted as R.1983 d.604, effective December 14, 1983. See: 15 N.J.R. 1708(b), 16 N.J.R. 48(a). Chapter 33 was repealed and a new Chapter 33, Certificate of Need: Application and Review, was adopted by R.1985 d.498, effective October 7, 1985. See: 17 N.J.R. 1190(a), 17 N.J.R. 2402(a).

Pursuant to Executive Order No. 66(1978), Chapter 33, Certificate of Need: Application and Review, was readopted as R.1990 d.417, effective July 27, 1990. See: 22 N.J.R. 1494(a), 22 N.J.R. 2506(a).

Subchapters 1 through 4 were repealed and a new Subchapter 1, General Provisions; Subchapter 2, Applicability of Certificate of Need Requirements; Subchapter 3, Types of Certificate of Need Applications; Subchapter 4, The Review Process; and Subchapter 5, Expedited Review Process, were adopted as new rules by R.1992 d.342, effective September 8, 1992. See: 24 N.J.R. 2222(a), 24 N.J.R. 3104(a). As a part of R.1992 d.342, Section 5.1 was recodified as 6.1.

Subchapter 6, Certificate of Need Moratorium, was repealed and a new Subchapter 6, Certificate of Need Exemptions, was adopted as new rules by R.1993 d.442, effective September 7, 1993. See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Subchapter 7, Direct Review Process, was adopted as R.1996 d.101, effective February 20, 1996. See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Pursuant to Executive Order No. 66(1978), Chapter 33, Certificate of Need: Application and Review, expired on September 8, 1997.

Chapter 33, Certificate of Need: Application and Review Process, consisting of 8:33-1.3, 8:33-3.11 and 8:33-5.1, was originally adopted as new rules by R.1998 d.278, effective June 1, 1998. See: 30 N.J.R. 1005(a), 30 N.J.R. 1991(a). The balance of the chapter was adopted as new rules by R.1998 d.303, effective June 15, 1998. See: 30 N.J.R. 303(a), 30 N.J.R. 2270(b).

Chapter 33, Certificate of Need: Application and Review Process, was readopted as R.2002 d.243, effective July 3, 2002. See: Source and Effective Date. See, also, section annotations.

Subchapter 7, Direct Review Process, was repealed by R.2002 d.243, effective August 5, 2002. See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

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APPENDIX

SUBCHAPTER 1. GENERAL PROVISIONS

8:33-1.1 Purpose and scope

(a) The purpose of these rules is to implement the provisions of the Health Care Facilities Planning Act, P.L. 1971, c.136, as amended by P.L. 1978, c.83, the Health Care Cost Reduction Act, P.L. 1991, c.187, the Health Care Reform Act, P.L. 1992, c.160, and the Certificate of Need Reform Act, P.L. 1998, c.43. These rules may be amended as necessary, in accordance with N.J.S.A. 52:14B-1 et seq., the Administrative Procedure Act, and N.J.A.C. 1:30, Rules for Agency Rulemaking, to best implement the statutory provisions and to reflect changing economic and systemic conditions within the health care system.

(b) These rules apply to the initiation, construction and/or expansion of all health care facilities and services as identified in the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. and/or Appendix Exhibits 1 through 4 of this chapter, incorporated herein by reference. Applicants for certificates of need are advised that the policies, standards, and criteria set forth in this chapter are in addition to, and not in limitation of, any other applicable certificate of need authorities, specifically including, but not limited to, those in N.J.S.A. 26:2H-1 et seq., the service-specific health planning rules, any applicable licensing authorities, or any specific conditions imposed upon facilities or services by the Commissioner in their particular certificate of need approvals.

(c) All inquiries regarding certificate of need matters should be directed to:

Certificate of Need and Acute Care Licensure
Program
New Jersey State Department of Health and
Senior Services
PO Box 360, Room 403
Health-Agriculture Building
John Fitch Plaza
Trenton, New Jersey 08625-0360
(609) 292-6552 and 292-7228

Amended by R.2002 d.243, effective August 5, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

In (a), inserted, “,” and the Certificate of Need Reform Act, P.L. 1998, c.43” following “1992, c.160” and “Rules for” following “N.J.A.C. 1:30”; in (b), inserted “3” for “4” in Exhibits; in (c), substituted “Room 403” for “Room 604” and added a phone number; deleted (d).

8:33-1.2 General statements of public policy and rules of general application

(a) It is the public policy of the State that access to health care services of the highest quality are of vital concern to the public health. Recognizing the significant changes in the economics of the health care system since the inception of the certificate of need program, decisions as to most health care services, acquisition of medical technology, and expansion of facilities can best be made by the health care provider. The appropriate role of the State with respect to services no longer subject to certificate of need is that of licensure of facilities and services to ensure the quality of care. For reasons of maintaining the quality of certain health care services, a limitation of the proliferation of such services may continue to be essential to protect the viability of the services as well as the providers now rendering them, to protect the role of such institutions as urban hospitals, whose importance to the Statewide health care system is indisputable, and to guard against the closing of important facilities and the transfer of services from facilities in a manner which is harmful to the public interest. Pursuant to N.J.S.A. 26:2H-1, to protect and promote the health of the inhabitants of the State, the Department shall have the central, comprehensive responsibility for the development and administration of the State’s policy with respect to health planning for all such health care facilities and services. Based on the particular needs of the State, this plan may include limiting the proliferation of certain health care services to preserve the viability of existing providers and urban hospitals, which play a vital role in the Statewide health care delivery system. The Department also must guard against the closing of important institutions and the transfer of services from facilities in a manner that is harmful to the public interest. All such health care facilities and services shall be subject to the provisions established herein.

(b) The Commissioner, to implement the provisions and purposes stated above, shall have the power to inquire into the accessibility to and availability of health care services and the operation of health care facilities and to conduct periodic inspections of such facilities with respect to the fitness and adequacy of the premises, equipment, personnel, rules and bylaws and the adequacy of financial resources and resources of future revenues.

(c) No certificates of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area(s) to be served, can be financially accomplished and maintained, licensed in accordance with applicable licensure regulations, will not have an adverse economic or financial impact on the delivery of or access to health care services in the region or Statewide, and will contribute to the orderly development of adequate and effective health care services. In making such determinations there shall be taken into consideration the availability of facilities or services which serve as alternatives or substitutes, the need for special equipment and services in the area, the adequacy of financial resources and sources of present and future revenues, the availability of sufficient human resources in the several professional disciplines, the accessibility to and availability of health care services to low income persons, and **such other factors** as may be established by regulation. In the case of an application by a health care facility established or operated by any recognized religious body or denomination, the needs of the members of such religious body or denomination for care and treatment in accordance with their religious or ethical convictions may be considered to be public need.

(d) Certificate of need applications shall be reviewed for conformance with the rules in effect on the date the application is accepted for processing or deemed complete for processing, as applicable.

(e) Recommendations concerning certificates of need shall be governed and based upon the principles and considerations set forth in these rules, as well as applicable State laws and rules.

(f) Certificates of need shall be issued by the Commissioner based upon criteria and standards promulgated by the Commissioner and approved by the Health Care Administration Board. (See N.J.A.C. 8:33 and the applicable chapter for specific services.) If any application is denied, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c.410 (N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq.), and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1 in accordance with N.J.S.A. 26:2H-9. Requests for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's action. The Department shall arrange for a hearing within 60 days of receipt of a request, and after such hearing the Commissioner or his or her designee shall furnish the applicant with the hearing examiner's written recommendations and reasons therefor. The Commissioner, within 30 days of receiving all appropriate hearing records, shall make his or her determination, which shall be a final agency decision.

(g) Projects involving building construction or renovations require submission of architectural plans to the Department of Community Affairs for approval prior to initiating building construction or renovations, in accordance with this chapter and the Department's licensing rules, regardless of whether the project requires a certificate of need or is exempt from the

certificate of need requirement. At project completion, written notification and a copy of the certificate of occupancy shall be submitted to the Department of Community Affairs for final approval of the project.

(h) Written notification or application for a license, as applicable, shall be submitted to the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, prior to the planned use of the beds, services or facility, in accordance with this chapter and the Department's licensing rules.

(i) Application for a license on forms prescribed by the Department shall be filed with the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, for approval prior to any transfer of ownership of beds, service or facility, in accordance with this chapter and the Department's licensing rules.

(j) No health care facility shall be operated unless it shall possess a valid license issued by the Department pursuant to N.J.S.A. 26:2H-1 et seq. The establishment of a new health care facility, the expansion of beds and services, and renovations or additions to health care facilities require approval from the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, prior to operation/occupancy of the beds, services or areas.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

Case Notes

Regulations reflect concern over those aspects of health care that relate to patient access as well as personnel policies affecting patient care. *Desai v. St. Barnabas Medical Center*, 103 N.J. 79, 510 A2d 662 (1986).

Certificate of need requirements as valid exercise of police power. *Merry Heart Nursing and Convalescent Home, Inc. v. Dougherty*, 131 N.J.Super. 412, 330 A.2d 370 (App.Div.1974).

8:33-1.3 Definitions

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

"Accepted for processing" means an application, subject to N.J.A.C. 8:33-5, has been determined by the Department as eligible to be entered into the applicable review cycle.

"Adolescent acute psychiatric beds" means licensed psychiatric beds in a designated and separate unit of a licensed general, psychiatric or special hospital, established for the provision of intensive treatment to persons generally between the ages of 13 and 18 who are experiencing an acute episode of a primary psychiatric disorder and have been medically evaluated to require the services of a specifically designated unit.

“Adult acute psychiatric beds” means licensed psychiatric beds in a designated and separate unit of a general, psychiatric or special hospital, established for the provision of intensive evaluation, stabilization and treatment of persons 18 years of age and older who are experiencing an acute episode of a primary psychiatric disorder. Patients are admitted under voluntary status.

“Adult closed acute psychiatric beds” means licensed psychiatric beds in a designated and separate unit of a general, psychiatric, or special hospital for the provision of treatment services for persons experiencing an acute episode of a psychiatric disorder. All such persons are referred by a designated psychiatric screening center and may be admitted voluntarily or involuntarily if they are determined to be mentally ill and dangerous to self or others.

“Adult intermediate psychiatric beds” means licensed psychiatric beds in a separate and designated area in a general, psychiatric or special hospital for the provision of intensive psychiatric evaluation and treatment services as part of a comprehensive psychiatric and psychosocial rehabilitation program, and which are appropriate for individuals aged 18 and above who are experiencing an acute episode of a psychiatric disorder and who require a comprehensive and specialized treatment program that cannot be fully provided within a short-term acute psychiatric setting. Admissions to the intermediate psychiatric unit or facility have an average length of stay which is generally greater than the average length of stay for adult acute psychiatric units in New Jersey and less than 45 days.

“Advanced life support” (ALS) means an advanced level of prehospital, interhospital, and emergency service care which includes basic life support functions, cardiac monitoring, cardiac defibrillation, telemetered electrocardiography, intravenous therapy, administration of specific medications, drugs and solutions, use of adjunctive ventilation devices, trauma care, and other techniques and procedures authorized by the Commissioner, pursuant to N.J.S.A. 26:2K-7.

“Ambulance service” means the provision of emergency or non-emergency medical care and transportation by certified personnel in a vehicle, which is designed and equipped to provide medical care at the scene and while transporting sick and/or injured persons to or from a medical care facility or provider.

“Applicant” means an individual, a partnership, a limited liability partnership, a corporation (including associations and joint-stock companies), a limited liability corporation, a State, or a political subdivision or instrumentality (including a municipal corporation) of a State that will be the licensed operator of the proposed service, facility or equipment, which will have overall responsibility for the health care service to be provided.

“Assisted living program” means the provision of or arrangement for meals and assisted living services, when

needed, to the tenants (also known as residents) of publicly subsidized housing which because of any Federal, State, or local housing laws, regulations or requirements cannot become licensed as an assisted living residence. An assisted living program may also provide staff resources and other services to a licensed assisted living residence and a licensed comprehensive personal care home.

“Assisted living residence” means a facility that is licensed by the Department to provide apartment-style housing and congregate dining and to assure that assisted living services are available when needed, to four or more adult persons unrelated to the proprietor. Apartment units offer, at a *minimum*, one unfurnished room, a private bathroom, a kitchenette, and a lockable door on the unit entrance.

“Atlantic Cardiovascular Patient Outcomes Research Team trial” or “Atlantic C-PORT-E trial” means the multi-state, randomized clinical trial being conducted by the Atlantic Cardiovascular Patient Outcomes Research Team under the direction of Thomas Aversano, M.D., Johns Hopkins Medical Institutions, comparing outcomes of elective PCI at hospitals with and without on-site cardiac surgery.

1. Atlantic C-PORT-E trial documents and other information can be obtained by contacting Thomas Aversano, M.D., Medical Director, Atlantic C-PORT-E, Johns Hopkins Medical Institutions, 5501 Hopkins Bayview Circle, JHAAC 1B.40, Baltimore, Maryland 21224, (410) 550-9820, http://www.cport.org/atlantic_cport_introduction_body.htm.

“Bed capacity” means the total number of beds, listed by health care service within the facility, which are recognized on the facility’s current license.

“Bloodless surgery” means the performance of surgery in a general hospital without the use of blood transfusion, including, but not limited to, adult cardiac surgery and exclusive of pediatric cardiac surgery, solid organ transplantation, high risk perinatal, and trauma surgery.

“Burn center” means a general hospital that provides the same comprehensive burn care services as required of a burn unit. In addition, a burn center provides intensive and comprehensive in-service training and education for all burn care personnel and includes a research component.

“Burn program” means a general hospital that provides therapy to burn patients, which includes fluid resuscitation and electrolyte balance, hydrotherapy, debridement, escharotomy, and shock prevention.

“Burn unit” means a general hospital that has beds committed solely to burn care, a large and diversified physician staff and nursing staff that rotate solely in this service. A burn unit shall provide electrocardiograph-oscilloscope defibrillation, cardiac output monitoring, physical therapy-hydrotherapy and occupational therapy.

SUBCHAPTER 3. TYPES OF CERTIFICATE OF NEED APPLICATIONS

8:33-3.1 Initiation of health care service

Establishment of any of the specified standard categories of health care services as referenced in N.J.S.A. 26:2H-1 et seq., as amended and/or as identified in the chapter Appendix, Exhibit 1, incorporated herein by reference, or the modification, replacement or expansion of any health care service or facility, regardless of the amount of capital or operating expenditures requires a certificate of need except as exempted by P.L. 1992, c.160, as amended by P.L. 1998, c.43 or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review or direct review process, except as provided for at N.J.A.C. 8:33-5.1(a).

Amended by R.2002 d.243, effective August 5, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Substituted "Exhibit 1" for "Exhibit 2" and "as amended by P.L. 1998, c.43 or otherwise exempted pursuant to" for "as stated in" following "P.L. 1992, c.160".

8:33-3.2 Termination/discontinuance of service or facility and/or reduction of licensed bed capacity

(a) Any health care facility which has closed or substantially ceased operation of any of its beds, facilities or services which require a certificate of need to be initiated, for any consecutive two-year period, shall be required to obtain a certificate of need before reopening such beds, facilities or services.

(b) Voluntary closure of a facility or discontinuance of all of its services does not require a certificate of need, except that the closure of a general hospital requires a certificate of need and shall follow the full review process. Applications for the closure of a general hospital shall be accepted on the first business day of any month. Where a certificate of need is not required pursuant to this section, written notification shall be filed with the Department's Certificate of Need and Acute Care Licensure Program, 30 days prior to the proposed closure of a facility or discontinuance of all of its services. Full compliance with all applicable Department requirements contained in this chapter and in service-specific chapters for closure/discontinuance shall be required.

(c) Discontinuance of a component service of a health care facility or satellite emergency department shall not require a certificate of need where the discontinuance will not result in problems of access to populations historically served and is not a service which is required to be a component of an inpatient health care facility. In these instances, the licensed entity shall notify the Department's Certificate of Need and Acute Care Licensure Program in writing 60 days prior to discontinuance of the service. Such notice shall include a rationale of why the licensed entity anticipates that discontinuance will not result in problems of access, including access to women's reproductive health services, where contextually applicable. The Department will notify the provider whether the proposed discontinuance requires a certificate of need. If a certificate of need is required, the certificate of need application shall follow the expedited review process set forth at N.J.A.C. 8:33-4.1(c). The provider shall not discontinue the service until the Department provides notice that no certificate of need is required or that a certificate of need is approved, as applicable.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

Case Notes

Required review of facility transfer documents by Division does not support facility's contention that Division is equitably estopped from seeking recovery of Medicaid over-payments. *Bridgeton Nursing Center, Inc. v. Div. of Medical Assistance and Health Services*, 8 N.J.A.R. 217 (1983).

8:33-3.3 Transfer of a health care service/facility

(a) A certificate of need is required for a transfer of ownership of the following:

1. An entire general hospital. Applications for such shall follow the full review process set forth at N.J.A.C. 8:33-4.1(a), and shall be accepted on the first business day of any month; and
2. A transfer that will result in a new Medicare provider number for the hospitals involved in the transfer. Applications for such shall follow the full review process set forth at N.J.A.C. 8:33-4.1(a).

(b) A certificate of need is not required for transfer of ownership of all other operating health care facilities, beds, services or equipment not specified in (a) above. Where a certificate of need is not required pursuant to this section, application for a license on forms prescribed by the Department shall be filed with the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, in accordance with this chapter and the Department's licensing rules.

(c) If a transfer of ownership occurs without a required certificate of need, then a daily penalty as established in the service-specific licensing rules promulgated by the Department may be assessed on the "new" owner and/or operator from the date of the unapproved transfer to the date the Department grants formal ownership approval to the "new" owner and/or operator.

(d) In the review of a transfer of ownership application, the prospective owner(s)/operator(s) shall be evaluated by the Department on the basis of character and competence and track record with regard to past and current compliance with state licensure, applicable Federal and certificate of need requirements, as specified in N.J.A.C. 8:33-4.9 and 4.10.

(e) A prospective owner approved for any transfer of ownership shall be subject to the same Department certificate of need, licensure, and reimbursement requirements as the current owner, including continuing compliance with any applicable certificate of need conditions, except that the Commissioner may amend the requirements to relate to changes in the health care system.

(f) These rules apply to ownership by any individual, partnership, limited liability partnership, corporation, limited liability corporation, or other entity in any entity which is the licensed operator of a facility or which owns the facility's real property. Except as otherwise provided in (h) below, a transfer of ownership which requires a certificate of need is defined as an acquisition or transfer which will increase or establish an ownership interest in a health care facility, as defined in N.J.A.C. 8:33-1.3, through purchase, lease, purchase or lease option, gift, donation, exchange, or by any other means. Types of ownership interests to which these rules apply include, but are not limited to, the following:

1. Shares of stock or any other type of security in a private business corporation;
2. Partnership interests in a general or limited partnership;
3. Ownership of a proprietorship or any other entity which operates a health care facility; and
4. Holding title to real property which is used to operate health care facility, or having a leasehold interest in such real property.

(g) Applications for transfer of ownership shall specify each and every principal in the entity which is the prospective owner and shall account for 100 percent of the ownership of the facility, except that if the ownership and operation is a publicly held corporation, each and every principal who has a 10 percent or greater interest in the corporation shall be identified by name, home address and percentage of interest.

(h) The following types of changes by operating health care facilities shall not require certificate of need approval

by the Department as transfers of ownership, but shall require prior written notice to the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, of any such sale and identification of ownership changes:

1. The purchase or sale of less than 10 percent of the outstanding stock (preferred or common) in a business corporation, except that any purchase of stock which results in an individual holding 10 percent or more of the corporation's outstanding stock when the individual previously held less than 10 percent of the stock shall require certificate of need approval;

2. The purchase or sale of limited partnership interests in a limited partnership, where a written limited partnership agreement prohibiting participation in management of the partnership by limited partners has been submitted to the Department. This exception shall not apply to general or managing partners or to any partner who participates in management;

3. A change in the membership of a nonprofit corporation, where the members are individuals or nonprofit corporations, and there is no purchase or sale of assets. In cases involving general hospitals, the facility shall provide notification documenting, to the satisfaction of the Commissioner, that the membership change does not diminish access to previously provided community services, including, but not limited to, women's reproductive health services. If the Commissioner determines that there will be decreased access to existing community services, a facility shall be required to file a certificate of need application. The application shall be subject to the expedited review process, as set forth at N.J.A.C. 8:33-5.2(c);

4. A change in ownership which does not involve acquisition of an ownership interest by a new principal; that is, the change involves only the percentage owned by the principals in the entity which is the licensed operator of the facility or involves withdrawal of one or more principals from ownership in the facility;

5. The death of a principal in a health care facility, which shall be reported to the Department's Certificate of Need and Acute Care Licensure Program or Long-Term Care Licensing and Certification Program, as applicable, together with the identity of the heir(s) to the ownership interest of the deceased principal. If the heir(s) intends to retain the ownership interest, the heir(s) shall be subject to investigation of licensure track record. Otherwise, the Department may accept an application to transfer the heir's ownership interest. Any other transfer of ownership which occurs by operation of law shall be reported in the same manner; and

6. A transfer, which involves a change in the controlling legal entity, but not in individuals with ownership interests, including, but not limited to:

i. A change in the type of organizational entity owning the facility only, with no change in the principals with ownership interests (for example, a change from a corporation to a partnership or vice versa);

ii. The merger or consolidation of a corporation with or into its wholly-owned subsidiary;

iii. The merger or consolidation of a corporation with or into a corporation with identical common ownership;

iv. A transfer of assets to an entity with identical common ownership;

v. A transfer of assets to a wholly-owned subsidiary corporation;

vi. A transfer of assets from a wholly-owned subsidiary corporation to its parent;

vii. A transfer of stock to a wholly-owned subsidiary; or

viii. A transfer of stock to an entity with identical common ownership.

(i) Any person or entity which loans money for the construction of, capital improvements to, or operation of a health care facility may hold as security therefore such liens, mortgages, pledges, and other encumbrances on the assets, real property, or stock or other ownership interests in the health care facility as provided in any loan or security agreement with the borrower and to the fullest extent permitted by law. If a lender acquires an interest in all of the assets or ownership of a health care facility upon foreclosure of any such security interest upon default, such lender shall promptly make application for a certificate of need in accordance with this subchapter and shall be permitted to operate the facility pending review and approval of said application provided that such lender shall demonstrate to the satisfaction of the Department that the health, safety and welfare of the patients will be maintained in the interim.

(j) Except as otherwise provided in (k) below, the transfer of unimplemented certificates of need is prohibited. Proceeding with any such transfer shall nullify the certificate of need and preclude licensure as a health care facility.

(k) At the discretion of the Department, an exception to the prohibition, at (j) above, on the sale of certificates of need prior to licensure may be permitted and the certificate of need process for transfer of ownership may be allowed to proceed on an unimplemented certificate of need if the types of changes set forth at (h)1 through 6 above apply. Applicants for transfers of unimplemented certificates of need shall demonstrate in the application that the transfer will not adversely affect the financial feasibility of the project.

(l) If a lender or creditor acquires an ownership interest in the physical assets of an unimplemented certificate of need project through foreclosure on a mortgage, lien, or other security interest, the certificate of need may be automatically nullified, based on the provisions of this chapter, except that the Commissioner may consider the transfer of the certificate of need to the new owner of the site where the certificate of need approved project has been substantially completed as determined by the Commissioner, and where the Commissioner finds that the completion of the project would be in the best interest of the population to be served and the entity acquiring ownership interest complies with track record requirements set forth at N.J.A.C. 8:33-4.10(d).

(m) If the facility being transferred has any partially implemented or unimplemented certificate of need approvals, an application for a license to own and/or operate the facility by the new owner will not be accepted by the Licensing Program unless the current owner/operator surrenders to the Department the unimplemented certificate of need approvals. The Commissioner may waive this requirement, based on a determination that the project has been substantially completed and that completion of the project is in the public interest, consistent with the principles set forth at N.J.A.C. 8:33-1.2.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-3.4 Changes in licensed beds and/or services

(a) The following criteria apply to changes in licensed beds and/or services:

1. Any increase in the number of licensed beds by licensure and/or health planning category requires a certificate of need unless the bed type is specifically exempted from the certificate of need requirement pursuant to P.L. 1992, c.160, as amended by P.L. 1998, c.43, section 19 (N.J.S.A. 26:2H-7a), or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review process, except as provided for at N.J.A.C. 8:33-5.1a.

2. Any decrease in the number of licensed beds by licensure and/or health planning category shall not require a certificate of need. Conversions of licensed beds to other uses shall be treated as increases in the number of beds by licensure or health planning category and the provisions of (a)1 above shall apply.

3. For services for which there is no specific licensed bed complement, relocation is not permitted, unless the service is otherwise exempt from the certificate of need requirement in accordance with those rules. For services for which there is a specific licensed bed complement, the

relocation of a portion of a facility's licensed beds or the entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region requires a certificate of need and shall follow the expedited review process, unless the beds or service at issue are otherwise exempt from the certificate of need requirement in accordance with these rules. The application shall be considered pursuant to the following criteria:

i. The relocation shall take place within the same planning region where the sending facility is located;

ii. The receiving facility shall already hold a license for the category of beds proposed for relocation. The Commissioner may, in the case of proposed bed relocations, waive this requirement when the receiving facility is the site of a general hospital proposed or approved for closure in the previous 12 months, if the Commissioner makes a finding that such approval will not reduce quality of care associated with the beds;

iii. The relocation shall not have an adverse impact on the ability of the population currently being served in the sending facility's service area to access the same types of service or bed complement as those proposed for relocation;

iv. The relocation shall not reduce access by the medically underserved and shall address the criteria set forth at N.J.A.C. 8:33-4.10(a);

v. The relocation shall not have an adverse impact on quality of care at either the sending or receiving facility;

vi. All minimum and maximum bed/unit size requirements (for example, six bed pediatric units, 10 bed obstetrics units, 240 bed long-term care facilities) shall be maintained at both the sending and receiving facilities; and

vii. The relocation shall not violate a condition of a prior certificate of need approved for the establishment of the beds or services, unless the applicant presents evidence of substantial changes since imposition of the condition and the Commissioner makes a finding that the evidence warrants removal or modification of the condition.

4. The relocation of a portion of a health care facility's licensed beds or an entire service, whether it has a bed-related component or not, from one licensed facility to another outside the same planning region shall not be permitted.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-3.5 Buildings

(a) The following criteria apply to buildings:

1. Regardless of cost, a certificate of need is required for the establishment of a new health care facility unless the facility type is specifically exempted from the certificate of need requirement pursuant to section 19 (N.J.S.A. 26:2H-7a), as amended by P.L. 1998, c.43, or otherwise exempted pursuant to this chapter. The certificate of need application shall be subject to the full review process, except as provided for at N.J.A.C. 8:33-5.1(a).

2. Replacement at the same site of an existing licensed health care facility that is subject to the certificate of need requirement shall be exempt from the certificate of need requirement, providing such replacement meets the following criteria:

i. The facility proposed for replacement is not licensed as a general hospital;

ii. The existing facility proposed for replacement is not adding beds or services within any licensure and/or health planning category that is subject to the certificate of need requirement to its total licensed bed or service complement not previously offered by the applicant at the existing facility already approved by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable;

iii. All direct patient services in the existing facility shall cease operation once the replacement facility is licensed; and

iv. The replacement facility shall be located at the existing site.

3. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement to a new site outside the same planning region as the existing facility site shall not be permitted.

4. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement to a location within the same planning region requires a certificate of need and shall follow the expedited review process, unless the facility is otherwise exempt from the certificate of need requirement in accordance with these rules, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3i through vii and as follows:

i. The facility proposed for replacement or relocation is not licensed as a general hospital;

ii. The existing facility proposed for relocation is not adding beds or services within any licensure and/or health planning category that is subject to the certificate of need requirement to its total licensed bed or service complement at the proposed replacement facility; and

iii. All direct patient services in the existing facility shall cease operation once the replacement facility is licensed.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-3.6 (Reserved)

Repealed by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Section was "New construction/modernization/renovation".

8:33-3.7 Major moveable equipment

(a) Applications to initiate full service or low risk invasive adult cardiac diagnostic services will only be accepted by the Department in accordance with the eligibility and application review criteria set forth in N.J.A.C. 8:33E. All such applications will be subject to the expedited certificate of need review process set forth at N.J.A.C. 8:33-5.

(b) Addition of cardiac catheterization equipment by a general hospital licensed to provide full service invasive cardiac diagnostic services is exempt from the certificate of need requirement.

(c) Replacement of cardiac catheterization equipment is exempt from the certificate of need requirement.

(d) Health care equipment which involves new technology that is not identified in this chapter shall not be subject to certificate of need requirements, but shall meet the following requirements:

1. The new technology shall be directly related to an already licensed health care service for which the provider has obtained a certificate of need, if applicable, and is already licensed;

2. The provider shall provide the Commissioner with written notice of the intent to initiate the new technology at least 60 days prior to the date the provider will begin use of the technology;

3. The new technology shall have pre-market approval from the Federal Food and Drug Administration and meet all other applicable State and Federal legal and regulatory requirements, if any;

4. The provider shall use the new technology in accordance with guidelines approved by the Joint Commission on Accreditation of Health Care Organizations until such time as the Department may adopt licensing standards for the new technology. The provider shall comply with the Department's licensing standards for the new technology upon adoption of applicable standards; and

5. The provider shall agree to submit to the Department patient information and other data concerning use of new technology. The provider shall submit data, as specified by the Department until such time as the Department determines that further reporting is not required.

(e) Upon a finding by the Commissioner that the provider's use of new technology is not in compliance with the provisions set forth in (d)1 through 5 above, the Commissioner may suspend the use of same.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-3.8 Minor moveable equipment

Regardless of capital cost, a certificate of need shall not be required for the acquisition, replacement, expansion or transfer by any person, including a physician, of minor moveable equipment.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

8:33-3.9 Changes in cost/scope

(a) A change in cost of an approved certificate of need is exempt from certificate of need review subject to the following:

1. The applicant shall file a signed certification as to the final total project cost expended for the project at the time of application for license for the beds/service with the Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable.

2. Where the actual total project cost exceeds the certificate of need approved total project cost and is greater than \$1,000,000, the applicant shall remit the additional certificate of need application fee due to the Certificate of Need and Acute Care Licensure Program. The required additional fee shall be 0.15 percent of the total project cost in excess of the certificate of need approved total project cost. Certified checks, cashiers' checks or money orders must be made payable to Treasurer, State of New Jersey.

3. The Department will not issue a license for the beds/service until the additional fee is remitted in full.

(b) The following criteria apply to a proposed change in location of an unimplemented certificate of need project:

1. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project within the same county shall be exempt from the certificate of need review re-

quirement, providing such change in the location meets the following criteria. A proposed change in location that is exempt from the certificate of need requirement requires the submission of a written proposal to the Certificate of Need and Acute Care Licensure Program addressing the following requirements. The applicant may not proceed with the change in location until written authorization is issued by the Department.

i. The change in location shall not have an adverse impact on the ability of the population to be served in the original application to access the beds or services proposed for relocation, as determined by the Department. A change in location which will have an adverse impact on the delivery of services to the population to be served in the original application, as determined by the Department, shall require a certificate of need review and follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3.

ii. The change in location shall not violate a condition of approval of the unimplemented certificate of need. A change in location shall not be permitted where the unimplemented certificate of need project is subject to a condition of approval specific to the location of the project;

2. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project outside the approved county but within the same planning region requires a certificate of need, and shall follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3. Changes in location to a proposed site outside the same applicable planning region are not permitted.

3. A proposed change to more than one location within the same county of an unimplemented certificate of need approved for the establishment of beds shall be exempt from the certificate of need requirement, provided such change in the location meets the following criteria. A proposed change in location that is exempt from the certificate of need requirement requires the submission of a written proposal to the Certificate of Need and Acute Care Licensure Program addressing the following requirements. The applicant may not proceed with the change in location until written authorization is issued by the Department.

i. The beds shall be relocated within the same county as stated in the original certificate of need application and approved by the Commissioner;

ii. The beds at each site shall be licensed to the identical operating entity identified as the applicant in the original certificate of need application;

iii. All minimum and maximum bed/unit size requirements, as set forth in these and applicable licensing rules, shall be maintained at each facility;

iv. The proposed change in location shall not have an adverse impact on the ability of the population proposed to be served in the original location to access the beds proposed for relocation;

v. The proposed change in location shall not violate a condition of approval of the unimplemented certificate of need. A proposed change in location shall not be permitted where the unimplemented certificate of need project is subject to a condition of approval specific to the location of the project; and

vi. Each facility shall comply with all applicable licensing requirements.

4. A proposed change to more than one location outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region shall follow the expedited review process, subject to the provisions set forth at N.J.A.C. 8:33-3.4(a)3. Changes in location to proposed sites outside the planning region are not permitted.

5. A proposed change to more than one location within the same county and outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region shall follow the process identified at (b)3 and 4 above.

(c) Any change in the total approved square footage to be renovated and/or constructed does not require a certificate of need.

(d) The following criteria shall apply to changes in beds, complement of major moveable equipment and array of services:

1. A certificate of need is not required for a change in scope to an unimplemented certificate of need which results in a reduction of beds, elimination of approved major moveable equipment or elimination of services providing the change does not violate a condition of certificate of need approval. In these instances, the applicant shall be required to provide notification in writing to the Department's Certificate of Need and Acute Care Licensure Program of the specific reductions in scope for approval by the Department prior to implementation. If the proposed reduction would result in a violation of a condition of approval, a certificate of need for change in scope shall be required and shall follow the expedited review process.

2. The Department shall not accept for processing the following changes in scope. Failure to implement the scope of the project as approved shall result in nullification of the unimplemented certificate of need and require the filing of a new certificate of need application in the next appropriate cycle.

i. Any increase in the number or category of approved beds that is subject to the certificate of need requirement, unless the increase is solely for the addition of assisted living or comprehensive personal care beds; or

ii. Addition/expansion of services approved within the application or any standard categories of health care services in Appendix Exhibit 1 that is subject to the certificate of need requirement.

(e) The following criteria apply to changes in service area, access or availability to the approved project, population served:

1. The Department shall not accept for processing the following changes in the scope of any unimplemented certificate of need. Failure to implement the scope of the project as approved shall result in nullification of the certificate of need and require the filing of a new certificate of need application in the next appropriate cycle.

i. Relocation of the proposed project outside the county for which it was originally approved, if the location was subject to a condition of certificate of need approval which prohibits relocation; or

ii. Change in the population served including percentage of Medicaid and medically indigent required to be served as a condition of certificate of need approval.

(f) Any modifications to the project as approved shall be reported to the Department's Certificate of Need and Acute Care Licensure Program in writing for review and approval prior to implementation.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-3.10 Duration of an unimplemented certificate of need

(a) The following criteria apply to the duration of a certificate of need:

1. The certificate of need shall be valid for a period of five years from the date of approval, or as specifically identified in a call for certificate of need applications, in the applicable health planning regulation or other public notice issued by the Commissioner.

2. If an applicant requires an extension of time beyond the expiration date of the certificate of need, an application for extension of time shall be filed 60 days prior to the current expiration date. The application shall be subject to the expedited review process at N.J.A.C. 8:33-5.1. The application shall not be deemed complete unless the applicant provides documentation that the project's financing remains in place and is sufficient to cover cost increases, and that local zoning and/or local building approvals have already been obtained. The application shall document the reasons for delays and proposed detailed time frame identifying the remaining time needed for the project to be approved and/or licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable. Where the Commissioner determines that the approval should be extended for an additional time beyond its current expiration date, he or she shall assign an expiration date, based on the criteria contained in (a)3 below. Where the Commissioner denies the request for extension, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c.410 (N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq.) and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, in accordance with N.J.S.A. 26:2H-9. Requests for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's action. The Department shall arrange for a hearing within 60 days of receipt of a request, and after such hearing the Commissioner or his or her designee shall furnish the applicant with the hearing examiner's written recommendations and reasons therefor. The Commissioner, within 30 days of receiving all appropriate hearing records, shall make his or her determination, which shall be a final agency decision.

3. If the project has not been licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, within the original or, if applicable, extended time frame identified within this subchapter, the certificate of need shall automatically be deemed to be terminated.

Amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).
Amended by R.2002 d.243, effective August 5, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).
Rewrote the section.

8:33-3.11 Demonstration and research projects

(a) Projects which satisfy the definition of a research project, as specified at N.J.A.C. 8:33-1.3, shall be exempt from certificate of need requirements as long as they are conducted exclusively for the purposes of investigational studies and scientific research.

(b) At the conclusion of the research project, the health care services and equipment provided in the course of the research shall no longer have certificate of need exemption status. At that time, if the services and equipment used are to be continued such that they shall be provided to the general population or where billings for such services or equipment shall occur or reimbursement received, a certificate of need where applicable shall be obtained in accordance with the provisions of this chapter and all other applicable health planning rules.

(c) This subsection sets forth the requirements for an inner city cardiac satellite demonstration project:

1. The purpose of an inner city cardiac satellite demonstration project, as defined in N.J.A.C. 8:33-1.3, is to test the hypothesis that permitting a licensed inner city teaching hospital to provide invasive therapeutic cardiac services at a satellite hospital within the same hospital system shall maintain or improve the financial stability of the inner city hospital and promote the continued provision of the full range of services and programs which it provides. This project allows qualifying hospital systems to generate greater revenue for inner city hospitals by enabling them to provide invasive therapeutic cardiac services at a satellite hospital, the benefits of which shall then be credited to the inner city hospital, thereby enabling the inner city hospital to improve access to and the quality of invasive therapeutic cardiac services to medically underserved populations.

2. Inner city cardiac satellite demonstration projects shall obtain a CN pursuant to the expedited review process set forth in N.J.A.C. 8:33-5 and in response to a call issued by the Department. All activities of both the inner city hospital and the satellite hospital shall be governed by the rules concerning cardiac surgery centers, at N.J.A.C. 8:33E.

3. In order to implement the demonstration project gradually, the Department shall accept no more than two certificate of need applications, for cardiac satellite demonstration projects in any consecutive 24-month period, beginning on July 1, 1998. In addition to meeting the remaining criteria set forth in this subsection, only those applicants providing convincing evidence that the proposed project shall increase access to invasive therapeutic cardiac services among minority and medically underserved populations through the increased revenue reasonably expected through implementation of the project, shall be accepted.

4. An inner city cardiac satellite demonstration project shall submit an application to the Department that, at a minimum, demonstrates that the proposed inner city cardiac satellite demonstration project satisfies the following criteria:

i. The inner city hospital shall be part of a multi hospital system and shall be a licensed teaching hospital

that provides a comprehensive complement of invasive therapeutic cardiac services;

ii. Prior to the provision of the invasive therapeutic cardiac services at the satellite hospital, and on a periodic basis thereafter as determined by the Department, the inner city hospital and the satellite hospital shall each comply with all licensure criteria governing the provision of invasive therapeutic cardiac services, including those contained within N.J.A.C. 8:43G-7;

iii. Net revenues generated from the provision of invasive therapeutic cardiac services at the satellite hospital shall be utilized to benefit the inner city hospital. Upon application, the inner city hospital shall provide to the Department a report prepared by an independent accounting firm approved by the Department. The report shall provide an estimated projection of the amount of net revenues and expenses expected as a result of the implementation of an inner city cardiac satellite demonstration project, together with the methodology utilized to calculate the reported net revenues. The methodology shall comport with fair market valuation of all costs and revenues. The report shall further set forth a plan demonstrating the manner in which reported net revenues shall be used to increase access to and the quality of invasive therapeutic cardiac services at the inner city hospital and to promote, generally, the financial stability of the inner city hospital and the continued provision of the full range of services and programs which it provides. Upon the conclusion of the first calendar year of operation of the inner city cardiac satellite demonstration project, and each year of operation thereafter, the inner city hospital shall provide to the Department an accounting, in a standardized format to be determined by the Department, containing the net revenues that have been utilized to benefit the inner city hospitals. In addition, a complete financial report from the satellite hospital shall be submitted to the Department, including all expenses and other financial information related to the invasive therapeutic cardiac center, and the services it provides. This report shall be submitted to the Department within 60 days after the close of each calendar year;

iv. The provision of invasive therapeutic cardiac services at a satellite hospital in accordance with this subsection shall not result in a diminution of the volume or quality of services at the inner city hospital, as compared to the volume and quality of services prior to the initiation of the demonstration project. Volume shall not decrease 20 percent or more below the previous level, and the quality shall not decrease, as measured by risk-adjusted mortality rates, compliance with nationally recognized quality improvement initiatives and other measures as determined by the Department on a case-by-case basis, depending upon the facts and circumstances. Upon application, the inner city hospital shall submit a plan that demonstrates how the volume and quality of the invasive therapeutic cardiac services at the inner city hospital will be maintained. Notwithstanding the foregoing, the inner city hospital shall satisfy the regulatory requirements set forth at N.J.A.C. 8:33E-2.3 that are applicable to invasive therapeutic cardiac procedures, governing volume and quality of services. If the Department determines that the volume at the inner city hospital has decreased by 20 percent or more, or the quality is lower to a degree, for a consecutive 12-month period, the Department shall have the authority to rescind the satellite hospital's license to operate its invasive therapeutic cardiac services, upon notice to the inner city hospital and a six-month period to cure the deficiencies. The Department's determination to rescind the inner city hospital's license hereunder shall be final;

v. The provision of invasive therapeutic cardiac services at the satellite hospital shall be subject to the governance of the inner city hospital and operated in accordance with the policies, procedures, and protocols of the inner city hospital which shall hold the license;

vi. Every inner city cardiac satellite demonstration project shall record and maintain data on the operation of the project, the patients served, the outreach to minority and indigent communities, and other information requested of each project by the Department. Such data shall be reported in a standardized format determined by the Department, and provided to the Department on a quarterly basis within 30 days after the close of each quarter;

vii. The inner city hospital shall ensure the provision of invasive therapeutic cardiac services at both the satellite hospital and the inner city hospital and shall assure that both hospitals comply and continue to comply with all applicable licensure rules.

5. All facilities seeking to initiate an inner city cardiac satellite demonstration project pursuant to an approved certificate of need issued in accordance with the demonstration criteria described in this subchapter shall be initially licensed on an annual basis, in accordance with the provisions of N.J.A.C. 8:43G.

2. Unless otherwise specified in these and other applicable rules, each demonstration application shall include the following:

- i. Documentation of exactly what is proposed to be demonstrated;
- ii. Patient care policies used as part of the demonstration, including criteria for inclusion/exclusion in the demonstration;
- iii. Proposed staff and staff qualifications for the demonstration;
- iv. Written documentation that otherwise eligible patients will be accepted into the demonstration regardless of ability to pay;
- v. Documentation of what data will be collected to evaluate the demonstration project; and
- vi. Written assurances that all data collected to evaluate the demonstration project shall be reported to the Department in accordance with requirements specified by the Department.

3. In the case of a demonstration that involves the addition of new beds or services otherwise subject to certificate of need, the applications shall be subject to review by the State Health Planning Board.

4. All demonstrations shall be approved for a period not to exceed two years unless otherwise specified in the call notice.

5. Approved demonstrations shall receive licensure approval from the Department to operate the service for the time period specified in the call notice plus the evaluation period specified by the Department in its approval letter, provided all applicable licensure standards are met.

- i. All applicants for demonstrations shall be notified in writing by the Department as to whether they shall be permitted continued operation of the service that is the subject of the demonstration within 60 days of the expiration date of the demonstration license;
- ii. Where the Department denies continuance of the demonstration project past the originally approved deadline, as set forth in (e)4 above, the demonstration project shall cease operating not later than 30 days after receipt of the written denial notice by the Department. Operators of denied demonstration projects shall have the right to appeal the Department's denial. A Notice of Appeal shall be sent to the Department within 30 days of receipt of the Department's denial notice. The appeal process shall comply with the requirements set forth in the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

6. All applicants, through a resolution of its Board of Directors, shall acknowledge and accept the standards and

criteria set forth for the demonstration as conditions of approval and agree to be bound thereto.

Amended by R.1998 d.303, effective June 15, 1998.

See: 30 N.J.R. 303(a), 30 N.J.R. 2270(b).

Inserted (a) and (b).

Amended by R.1999 d.272, effective August 16, 1999.

See: 31 N.J.R. 950(a), 31 N.J.R. 2375(a).

Added (d).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

Public Notice: Certificate of Need and Acute Care Licensure.

See: 36 N.J.R. 4996(b).

Amended by R.2007 d.387, effective December 17, 2007.

See: 39 N.J.R. 3462(a), 39 N.J.R. 5316(b).

Added new (e); and recodified former (e) as (f).

Case Notes

Although N.J.A.C. 8:33-3.11(e) authorized a call made by the Commissioner of the Department of Health and Senior Services that invited health care facilities without a cardiac surgery facility on site to apply for a certificate of need to conduct elective angioplasty, the regulation, as applied, violated fundamental principles relating to the regulatory process; as a result, certificates of need granted for demonstration projects were not sustainable and the projects were directed to continue only through November 30, 2007, and the Commissioner was directed to promulgate proper regulations, after appropriate adherence to the principles of rulemaking, before any such demonstration project could be continued. *Cooper Univ. Hosp. v. Jacobs*, 191 N.J. 125, 922 A.2d 731, 2007 N.J. LEXIS 600 (2007).

SUBCHAPTER 4. THE REVIEW PROCESS

8:33-4.1 Review cycles and submission dates

(a) The full review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The Commissioner shall publish in the New Jersey Register in February of each year an anticipated schedule for receipt of certificate of need applications subject to full review procedures for a two-year period, including the current calendar year. The Commissioner may announce additional or special calls for certificate of need applications beyond those identified in the yearly notice or may delete announced calls from the yearly notice. Changes to the published schedule shall be published in the New Jersey Register. Wherever practical, the Commissioner shall provide notice in accordance with this section to allow for a minimum of 90 days between the date of publication of the Commissioner's notice inviting certificate of need applications and the date for submission of applications in response to the notice(s). The notice shall identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, and the date the application is deemed complete for processing. The State Health Planning Board shall forward recommendations to the Commissioner within 90 days after the application is deemed complete for processing unless a fair hearing is requested by an applicant in accordance with the procedures identified at N.J.A.C. 8:33-4.14. For batches with fewer than 20 applications, a final agency decision will be rendered by the Commissioner no later than 120 days after

receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable. For batches with 20 or more applications, a final agency decision will be rendered by the Commissioner no later than 180 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable.

1. The full review process for non-batched applications shall include 12 review cycles. The beginning of each cycle shall be the first business day of each month.

2. The full review process for batched applications shall be in accordance with the following schedule, except that if the first of the month the application is due falls on a Saturday, Sunday, or State holiday, the application shall be filed the first business day of the month in which the application is due:

<u>Category</u>	<u>Deadline for Submission</u>
Long-term care, specialized ventilator	1/2/03 and annually thereafter
Long-term care, specialized behavior modification	1/2/03 "
Long-term care, pediatric	1/2/03 "
Maternal and child health	1/2/03 "
Pediatric intensive care	9/1/02 "
Psychiatric beds	2/1/03 and every two years thereafter
Rehabilitation beds	3/1/03 "
Children's hospitals	4/1/04 and every three years thereafter
Transplantation	4/1/04 "
Mobile intensive care unit	6/1/04 "
Trauma	6/1/04 "
Long-term care, general	7/1/04 "
Home health	7/1/04 "
Burn center, program, unit	4/1/06 and every five years thereafter
New general hospitals	4/1/06 "

3. Acceptance of batched applications submitted in accordance with the schedule in (a)2 above does not constitute a finding by the Department of need for the additional beds or services proposed in the application(s).

4. For services with longer than annual submission schedules, the Commissioner may announce special calls for receipt of certificate of need batched applications upon making a finding of extraordinary circumstances that warrant such a call prior to the next scheduled submission date.

5. The Department shall review the schedule in (a)2 above for adequacy at least every five years.

6. New cardiac surgery services shall follow the procedures specified at N.J.A.C. 8:33E.

(b) The expedited review process involves review of a certificate of need application by the Department. It does not include a review by the State Health Planning Board. The expedited review process will include 12 review cycles. The beginning of each cycle shall be the first business day of each month and a decision the Commissioner shall render shall be

rendered by the Commissioner no later than 90 days thereafter, unless otherwise specified by rule or notice.

(c) The Department shall conduct an annual review of the certificate of need application and review process to determine timeliness in processing certificate of need applications. Failure by the Department to process at least 90 percent of certificate of need applications filed within the year within the timeframes stated herein shall result in immediate corrective action.

Public Notice: Invitation for Certificate of Need Applications. See: 24 N.J.R. 4426(b); 25 N.J.R. 2596(c); 25 N.J.R. 4520(b), 25 N.J.R. 4795(e).

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Public Notice: Invitation for Certificate of Need Applications.

See: 34 N.J.R. 2473(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

Public Notice: Invitation for Certificate of Need Applications.

See: 34 N.J.R. 3991(b), 4226(a).

Public Notice: Certificate of Need and Acute Care Licensure.

See: 35 N.J.R. 277(a), 277(b).

Public Notice: Invitation for Certificate of Need Applications.

See: 35 N.J.R. 1739(c).

Public Notice: Certificate of Need: Application and Review Process.

See: 35 N.J.R. 4789(c), 5444(c).

Public Notice: Cancellation of Certificate of Need.

See: 36 N.J.R. 1834(a), 1835(a), 1835(c), 1836(a), 1836(b), 2263(a), 4997(a), 5460(a), 5460(b), 5460(c), 5460(d), 5461(a).

Public Notice: Cancellation of Certificate of Need Calls.

See: 37 N.J.R. 4580(a), 4580(b).

Public Notice: Invitation for Certificate of Need Applications.

See: 38 N.J.R. 1474(a), 1773(a).

Public Notice: Cancellation of Certificate of Need Calls.

See: 38 N.J.R. 5416(a).

Public Notice: Cancellation of Certificate of Need Calls.

See: 39 N.J.R. 802(a), 802(b), 802(c), 802(d), 803(a), 803(b), 803(c), 803(d), 804(a), 804(b).

Case Notes

Commissioner of Health failed to comply with procedural requirements in granting certificate of need. Matter of Bloomingdale Convalescent Center, 233 N.J.Super. 46, 558 A.2d 19 (A.D.1989).

Reliance on ranking of local advisory board to approve application for certificate of need with highest priority was not unreasonable. Application of Staff Builders Services, 95 N.J.A.R.2d (HLT) 30.

8:33-4.2 Development of applications

(a) Application for a certificate of need shall be made to the Department, in accordance with the requirements of this chapter, and shall be in such form and contain such information as the Department may prescribe.

(b) Before filing an application, applicants are encouraged to contact the Department to examine the relationship of the proposed project to the applicable plans, guidelines, and criteria.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote (b) and deleted (c).

8:33-4.3 Submission of applications

(a) Thirty-five copies of the application shall be submitted to:

Certificate of Need and Acute Care Licensure
Program
New Jersey State Department of Health and
Senior Services
PO Box 360, Room 403
John Fitch Plaza
Trenton, New Jersey 08625-0360
(609)292-6552, or 292-7228

(b) Below is the schedule of fees, based on total project costs, required when submitting any application for a certificate of need for the expedited, direct, or full review process. Fees shall be paid in full at the time applications are filed. Failure to pay the appropriate application filing fee in full shall cause the application not to be accepted for processing. Certified checks, cashiers' checks or money orders must be made payable to Treasurer, State of New Jersey. No cash or personal checks will be accepted. The certificate of need application fee shall be non-returnable, except that, if an application is submitted in the incorrect batch, is unresponsive to the notice issued by the Commissioner or inappropriately requests expedited review, it may be declared not acceptable for processing by the Department, in which case the filing fee will be returned.

1. Establishment of a facility or service; Change in the capacity of an existing facility or service; Acquisition of major moveable equipment:

<u>Total Project Cost (TPC)</u>	<u>Fee Required</u>
\$1,000,000 or less	\$5,000
Greater than \$1,000,000	\$5,000 + 0.15% of TPC
2. Change in scope:	\$5,000
3. Change in cost for \$1,000,000 or more	0.15% of additional project cost over \$1,000,000
4. Extension of time	\$5,000
5. Transfer of ownership	\$5,000

Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).
Amended by R.2002 d.243, effective August 5, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).
Rewrote the section.

8:33-4.4 Certificate of need filing requirements

(a) An applicant shall document in the application that he or she owns the site where the facility, service, or equipment will be located, or has an ownership or lease option for such site, which option is valid at least through the certificate of need processing period. A duly executed copy of the deed, option or lease agreement for the site shall be submitted with the certificate of need application and include identification of site, terms of agreement, date of execution and signature of all parties to the transaction. If the site is optioned or leased by the applicant, a copy of the deed held by the current owner shall be required at the time of filing.

(b) One hundred percent of the operation of the proposed facility, service or equipment shall be accounted for in the certificate of need application. Each and every principal involved in the proposal shall be identified by name, home address and percentage of interest, except that, if the operation is a publicly held corporation, each and every principal who has a 10 percent or greater interest in the corporation shall be identified by name, home address and percentage of interest. Where a listed principal has an operating interest in another health care facility, in this or any other state, identification of the principal(s), the health care facilities in which they have an operating interest, and the nature and amount of each interest shall be specified.

(c) If the applicant is a registered corporation, the name and address of the registered agent shall be identified in the application.

(d) The operator of the proposed facility, service, or equipment shall file and sign the application. In the case of transfer of ownership the proposed owner/operator is considered to be the applicant. However, both the current owner/operator and proposed owner/operator shall file and sign the application.

(e) If the applicant does not comply with all of the provisions in (a) through (d) above, the Department shall determine the application to be not acceptable for processing.

Amended by R.2002 d.243, effective August 5, 2002.
See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).
Rewrote the section.

8:33-4.5 Review for completeness

(a) Only complete applications shall be processed. The Department alone shall make the determination of the completeness status of applications. The Department shall make a decision on the completeness status of an application after the applicant has been given the opportunity to supplement the application within a specified timeframe in response to specific questions by the Department. The Department shall then make a decision on the completeness of the application. The Department shall notify the applicant of its determination. Upon issuing a determination that an application is complete, copies thereof shall be referred by the Department to the State Health Planning Board for review. If an application has been determined to be incomplete, the Department shall notify the applicant in writing citing the specific deficiencies in the application. The filing fee shall not be returned. The applicant may file a new application in the next appropriate cycle with the appropriate information.

(b) An application which is unresponsive to the notice issued by the Commissioner, or inappropriately requests expedited review may be declared not acceptable for processing by the Department, based on the standards contained in the chapter and the applicable service-specific chapter. The Department shall notify the applicant of this decision and the filing fee shall be returned.

(c) Once an application has been submitted to the Department, no subsequent submission of information shall be accepted, unless specifically requested in writing by the Department. Questions from the State Health Planning Board shall be transmitted by the Department to the applicant. Responses to all questions shall be forwarded to the Department for dissemination to the State Health Planning Board.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section

Public Notice: Invitation for Certificate of Need Applications.

See: 38 N.J.R. 1474(b).

Case Notes

Although N.J.A.C. 8:33-4.5(b) establishes the New Jersey Department of Health and Senior Services' discretion not to review certificate of need (CN) applications that are unresponsive to the notices sent out by the Commissioner of the Department, it does not require the Department to reject aspects of CN applications that go beyond the specific needs identified in the call but relate to it. In re Virtua-West Jersey Hosp. Voorhees, 390 N.J. Super. 444, 915 A.2d 1074, 2007 N.J. Super. LEXIS 42 (App.Div. 2007).

Denial of application for certificate of need to operate medical center hospice was not unreasonable when based on lack of area need. Matter of Community Medical Center/HHP, 95 N.J.A.R.2d (HLT) 27.

8:33-4.6 Modification of applications

(a) Under no circumstances shall an application be modified or altered to change the number or category of inpatient beds, proposed services, equipment subject to a planning regulation, proposed operator, or change in site after the application submission deadline date. An applicant desiring to make such a modification or alteration shall be required to withdraw the application from the current cycle and submit a new application for the next cycle.

(b) Modifications not specified in (a) above, such as changes in square footage and change in cost, shall be permitted if such changes are in response to completeness questions from the Department and made prior to submission of the application to the review process.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

In (a), inserted "proposed operator," following "planning regulation,".

8:33-4.7 Deferral of applications

(a) An applicant may request in writing a deferral for up to a total of six months for an individual application that is not competitive or comparatively reviewed. If the applicant fails to notify the Department in writing to reactivate the application within this time frame, a new application shall be required. An applicant may not defer an application submitted in a competitive or comparatively reviewed batch. If the applicant does not wish to proceed in the review process, the application shall be withdrawn.

(b) The State Health Planning Board or the Department may defer an individual certificate of need application where

the application is not competitive or comparatively reviewed with other applications. Where projects are competitive or comparatively reviewed, the State Health Planning Board or the Department may defer the entire batch or only those projects which are competitive or comparatively reviewed. The basis for any deferral shall be specified in writing to the applicant. The period of deferral of an individual certificate of need application, all projects in a batch which are competitive or comparatively reviewed, or an entire batch of certificate of need applications may not exceed six months.

(c) An applicant may revise the deferred project costs to account for inflation and may be requested by the Department to submit additional updated information prior to reactivation of the application.

1. Reactivated applications with no changes or with only a change in cost may continue in the review process from the point of deferral.

2. Reactivated applications with any change in project scope shall be treated as a new application and shall follow the review process beginning with submission of the application to the Department, except that if the application is modified in a non-substantive way, that is, if the modification were proposed separately, it would either not require certificate of need review or would require only an expedited review, the application may continue from the point of deferral.

(d) The Department shall not accept any requests for a deferral from the applicant once the State Health Planning Board has made its recommendation.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-4.8 Withdrawal of applications

An applicant may submit a written request for withdrawal of its application prior to final action by the Commissioner. The certificate of need filing fee shall not be returned in the event of a withdrawn application. Once an action has been taken by the Commissioner, the application shall not be withdrawn.

8:33-4.9 General criteria for review

(a) No certificate of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be financially accomplished and licensed in accordance with applicable licensure regulations, will not have an adverse impact on access to health care services in the region or State-wide, and shall contribute to the orderly development of adequate and effective health care services. In making such determinations there shall be taken into consideration:

(c) When conditions are included in the Commissioner's approval letter, the applicant shall file a progress report on meeting such conditions with the Certificate of Need and Acute Care Licensure Program at least 12 months from the date of approval and annually for the first two years after project implementation and at any other time requested by the Department in writing. Failure to file such reports may be taken into consideration in the review of subsequent certificate of need applications, result in fines and penalties imposed through licensure action and/or result in the nullification of the unimplemented certificate of need.

(d) Where an applicant has failed to meet conditions of approval of previously approved certificates of need, it may form an adequate basis for the Department to bar the applicant from filing any subsequent certificate of need until the conditions in question are satisfied.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

In (a), deleted "and local advisory board" following "Planning Board"; in (c), rewrote the last sentence.

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.1 Statement of purpose

(a) The expedited review process shall be used for the following types of applications:

1. Establishment of a Statewide restricted admissions facility or increase in bed capacity of a Statewide restricted admissions facility;
2. Change in scope to an unimplemented certificate of need;
3. Establishment of or increase in the bed capacity of comprehensive personal care homes;
4. Establishment of or increase in the capacity of assisted living residences;
5. Establishment of assisted living programs;
6. Extension of time to an unimplemented certificate of need;
7. Conversion of existing, on-site, licensed residential health care beds to long-term care beds for long-term care facilities located in Newark, Jersey City, Paterson, Atlantic City, Camden, Elizabeth, Trenton, Irvington, East Orange or Union City that were issued a certificate of need between January 20, 1987 and September 8, 1992 pursuant to the methodology contained in then existing N.J.A.C. 8:33H-3.3(b)3 and were licensed on or before August 17, 1998;

8. Establishment of demonstration projects in accordance with applicable planning rules;

9. Establishment of a cardiac catheterization program or emergency or primary coronary angioplasty (PTCA) services with off-site cardiac surgery backup in accordance with N.J.A.C. 8:33E;

10. Establishment of a special hospital providing long term acute care services in accordance with the Department's licensure standards at N.J.A.C. 8:43G-38;

11. The relocation of a portion of a health care facility's licensed beds or an entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region, unless the beds or service at issue are otherwise exempt from the certificate of need requirement; and

12. The relocation of an entire licensed health care facility that is subject to the certificate of need requirement, except for general hospitals, within the same planning region.

(b) The expedited review process may also be used in lieu of the full review process, or in the following limited situations:

1. Emergency situations which demand rapid action; or
2. When the project has minimal impact on the health care system as a whole.

Amended by R.1998 d.303, effective June 15, 1998.

See: 30 N.J.R. 303(a), 30 N.J.R. 2270(b).

In (a), inserted 1 through 23 and 25; and added (b).

Amended by R.1998 d.429, effective August 17, 1998.

See: 30 N.J.R. 1701(a), 30 N.J.R. 3080(a).

In (a), inserted a new 24, and recodified former 24 and 25 as 25 and 26.

Amended by R.1999 d.272, effective August 16, 1999.

See: 31 N.J.R. 950(a), 31 N.J.R. 2375(a).

Inserted (a)27.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-5.2 Process

(a) The expedited review process shall include 12 review cycles, where permitted by applicable planning regulations. The beginning of each cycle shall be the first business day of each month and a decision shall be rendered by the Commissioner no later than 90 days after the application has been accepted for processing.

(b) The determination of whether or not a project is accepted for processing under the expedited review process shall be made by the Department.

(c) Applications shall be reviewed to determine whether they are acceptable for processing. An original and nine copies of a signed and dated application, completely and accurately filled out shall be accompanied by the correct

application fee and 10 copies of out-of-State track record reports. Applications not meeting these requirements shall not be accepted for processing. The Department shall notify the applicant of this decision and the filing fee shall be returned. The applicant may file a new application with the appropriate information in the next appropriate application submission cycle.

(d) Certificate of need applications subject to expedited review shall be reviewed in accordance with the requirements of this chapter, the Department's licensing rules and applicable health planning rules.

(e) Certificate of need application forms for expedited review may be obtained from the Department at the address listed below. Applicants should contact staff of the Certificate of Need and Acute Care Licensure Program before filing an application to be certain that they have a copy of the most recent version of the Department's application. Applications other than the Department's most recent version shall not be accepted for processing. An original and nine copies of the application shall be filed with:

Certificate of Need and Acute Care Licensure Program

New Jersey State Department of Health and Senior Services

John Fitch Plaza

PO Box 360, Room 403

Trenton, New Jersey 08625-0360

(609)292-6552, or 292-7228

(f) Applications shall be reviewed by appropriate Department staff for the purpose of providing information to assist the Commissioner in making the final decision.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-5.3 General requirements

(a) Minimum information required for all expedited review projects shall consist of:

1. Project description, including changes in beds, total project cost, services affected, equipment involved, source of funds, utilization statistics, both inpatient and outpatient, and justification for the proposed project;

2. The extent to which all residents of the area shall have access to services, particularly the medically underserved; and

3. Applicants for all services proposed for expedited review at N.J.A.C. 8:33-5.1(a), shall document that the following criteria shall be met:

- i. Appropriate licensing and construction standards; and

- ii. Licensure track record requirements (N.J.A.C. 8:33-4.10(d)); and

4. Additionally, cardiac catheterization program applicants shall comply with all relevant sections of N.J.A.C. 8:33E.

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-5.4 Specific requirements

(a) In addition to the requirements of N.J.A.C. 8:33-5.3, the following information shall be provided, as appropriate, for all expedited review projects:

1. For an applicant who applies under the expedited review process to convert existing, on-site, licensed residential health care beds to long-term care beds in accordance with N.J.A.C. 8:33-5.1(a)7:

- i. A commitment that they will accept as a condition of certificate of need approval to maintain a minimum of 50 percent bed occupancy by direct Medicaid-eligible patients, of which 10 percent shall be discharged psychiatric patients from State and county hospitals. The aforesaid 50 percent and 10 percent bed minimums shall be calculated using the entire licensed bed capacity for the facility, shall be achieved no later than one year from approval, and shall be maintained at all times thereafter.

- ii. A commitment that they will accept as a condition of certificate of need approval that the conversion of residential health care beds to long-term care beds shall occur within the city limits of the city identified in the application and the applicant shall not relocate all or any portion of the facility's total licensed long-term care capacity outside of the city limits.

2. For the relocation of a portion of a health care facility's licensed beds or an entire service from one licensed facility (sending facility) to another (receiving facility) located within the same planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.4(a)3.

3. For a proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need outside the approved county but within the same planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.9(b)2.

4. For a proposed change to more than one location outside the county of an unimplemented certificate of need approved for the establishment of beds, but within the same applicable planning region, applicants shall document compliance with the requirements set forth at N.J.A.C. 8:33-3.9(b)4.

Amended by R.1993 d.442, effective September 7, 1993.

See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.1998 d.429, effective August 17, 1998.

See: 30 N.J.R. 1701(a), 30 N.J.R. 3080(a).

In (a), added 4.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

SUBCHAPTER 6. CERTIFICATE OF NEED EXEMPTIONS

8:33-6.1 Statement of purpose

(a) In accordance with the provisions of the Health Care Reform Act, P.L. 1992, c.160 and the Certificate of Need Reform Act, P.L. 1998, c.43 and N.J.S.A. 26:2H-7.2, the following specific health care services or projects are exempt from the certificate of need requirement:

1. Community-based primary care centers, as defined at N.J.A.C. 8:33-1.3, which provide preventive, diagnostic, treatment, management, and reassessment services exclusively on an outpatient basis to individuals with acute or chronic illnesses in a location and manner that is accessible to individuals;

2. Outpatient drug and alcohol services which include drug-free and methadone maintenance services and day treatment alcohol services;

3. Ambulance and invalid coach services, excluding mobile intensive care unit services;

4. Mental health services which are non-bed related outpatient services including outpatient centers, partial hospitalization programs and case management programs;

5. Residential health care facilities;

6. Transfer of ownership interest, except in the case of a general hospital;

7. Change of site for an unimplemented certificate of need within the same county;

8. Relocation or replacement of a health care facility within the same county, except for a general hospital;

9. Continuing care retirement communities authorized: pursuant to P.L. 1986, c.103 (N.J.S.A. 52:27D-330 et seq.) which contain a minimum of four independent living units for every one long-term care bed;

10. Magnetic resonance imaging;

11. Adult day health care facilities;

12. Pediatric day health care facilities;

13. Chronic or acute renal dialysis facilities;

14. Hospital-based medical detoxification for drugs and alcohol;

15. Capital improvements and renovations to health care facilities;

16. Addition of medical/surgical, adult intensive care, adult critical care beds in general hospitals;

17. Replacement of existing major moveable equipment;

18. Inpatient operating rooms;

19. Adult family care programs;

20. Hospital-based subacute care;

21. Ambulatory care facilities;

22. Comprehensive outpatient rehabilitation services;

23. Special child health clinics;

24. Addition of vehicles or hours of operation of a mobile intensive care unit;

25. Basic obstetric and pediatric services and birth centers, including addition of basic obstetric and pediatric beds in general hospitals;

26. Linear accelerators, including Cobalt 60 units;

27. New technology in accordance with the provisions set forth in N.J.A.C. 8:33-3.7(f);

28. Extracorporeal shock wave lithotripter;

29. Hyperbaric chamber;

30. Positron emission tomography;

31. Residential substance abuse treatment services;

32. Ambulatory surgical facilities;

33. Same day surgery operating rooms;

34. Long-term care facilities proposing to increase their total number of licensed long-term care beds by no more than 10 beds or 10 percent of their licensed long-term care capacity, whichever is less, within a period of five years pursuant to N.J.S.A. 26:2H-7.2;

35. Satellite emergency department;

36. A change in cost subject to the provisions set forth in N.J.A.C. 8:33-3.9(a);

37. Replacement at the same site of an existing licensed health care facility in accordance with the provisions set forth in N.J.A.C. 8:33-3.5(a)2; and

38. A proposed change in location of the entire complement of beds and services approved in an unimplemented certificate of need project within the same county in accordance with the provisions set forth in N.J.A.C. 8:33-3.9(b)1.

Amended by R.1996 d.101, effective February 20, 1996.

See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

8:33-6.2 Process

(a) This section shall apply to projects which are exempt from the certificate of need requirement.

1. For continuing care retirement communities, a certificate of authority from the Department of Community Affairs for the operation of a continuing care retirement community shall be submitted to the Department prior to licensure of the long-term care beds.

2. If an applicant for licensure of a health care service or facility that is not subject to certificate of need review so requests, the Department shall provide the applicant with a pre-licensure consultation. The purpose of the consultation is to provide the applicant with information and guidance on rules, regulations, standards and procedures appropriate and applicable to the licensure process and licensure requirements. The Department shall conduct the consultation within 60 days of receipt of the request of the applicant.

Amended by R.2002 d.243, effective August 5, 2002.

See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).

Rewrote the section.

SUBCHAPTER 7 (RESERVED)

APPENDIX

EXHIBIT 1

Health Care Services

A. Bed-related

- 1. Pediatric intensive or critical care
2. Comprehensive rehabilitation
3. General long-term care
4. Specialized long-term ventilator care
5. Specialized long-term care for severe behavior management
6. Pediatric long-term care
7. Adult acute psychiatric (open and closed)

- 8. Adult intermediate and special psychiatric
9. Child and adolescent acute psychiatric
10. Child and adolescent intermediate psychiatric
11. Long term acute care

B. Non-bed-related

- 1. Home health agency

C. Special Services

- 1. Invasive cardiac diagnostic services
2. Invasive therapeutic cardiac services
3. Burn center, unit or program
4. Organ transplant/organ procurement
5. Perinatal services including neonatal intensive or intermediate services and maternal and child health consortia
6. Mobile intensive care or advanced life support services
7. Comprehensive personal care home
8. Assisted living residence
9. Bone marrow transplant/harvesting including stem cell
10. Trauma services
11. Specialty acute care children's hospitals
12. Emergency medical service helicopters
13. Central service agency
14. Community Perinatal Center-Intermediate
15. Community Perinatal Center-Intensive
16. Regional Perinatal Center
17. Assisted living program
18. Any service for which regionalization criteria or health planning regulations have been developed.

EXHIBIT 2

Examples of Major Moveable Equipment

Cardiac catheterization laboratory equipment

EXHIBIT 3

Certificate of Need Review

BED-RELATED HEALTH CARE FACILITY/SERVICES

NEW/EXPANSION

Table with 2 columns: NEW/EXPANSION and TYPE OF REVIEW. Rows include Adult family care, Assisted living program, Assisted living residence, Burn center, unit or program, Comprehensive personal care home, General hospital, Hospital-based subacute care unit, ICU/CCU beds (adult), Medical detoxification program (hospital based), Medical/surgical, Long term acute care, Long-term care facility, General long-term care, Pediatric long-term care, Specialized long-term ventilator care, Specialized long-term care for behavior management, Statewide restricted admissions facility, Obstetric service.

<u>NEW/EXPANSION</u>	<u>TYPE OF REVIEW</u>	<u>NEW/EXPANSION</u>	<u>TYPE OF REVIEW</u>
Pediatric service (excluding intensive/critical care) ...	Exempt	Mobile intensive care unit (additions to vehicles or hours of operations)	Exempt
Pediatric service (intensive/critical care)	Full	Operating rooms	Exempt
Psychiatric hospital		Organ bank	Full
Acute	Full	Organ transplantation/procurement	Full
Intermediate and special	Full	Perinatal service: Maternal and Child Health Consortia	
Rehabilitation hospital (in-patient)	Full	New service	Full
Residential health care facility	Exempt	Change in membership	Full
Residential substance abuse treatment facility	Exempt	Perinatal service: Regional Perinatal Center, CPC-Intensive	
Special hospital	Full	CPC-Intermediate	
Specialty acute care children's hospital	Full	New service and designation	Full
DECREASE IN BEDS	Exempt	Change in designation	Full
REPLACEMENT OF BEDS	Exempt	Increased number of intermediate or intensive bassinets	Full
RELOCATION OF LICENSED BEDS OR AN ENTIRE SERVICE SUBJECT TO CN REVIEW		Perinatal service: CPC-Basic, CPC-Birth Center	
Within the same planning region in accordance with N.J.A.C. 8:33-3.4(a)3	Expedited	Designation	Exempt
RELOCATION OR REPLACEMENT OF AN ENTIRE LICENSED BED RELATED FACILITY SUBJECT TO CN REVIEW		Positron emission tomography scanning	Exempt
General hospital/within or outside county	Full	Satellite emergency department	Exempt
All other/within same planning region in accordance with N.J.A.C. 8:33-3.5(a)4	Expedited	Special child health clinics providing tertiary services	Exempt
All other/at the same site in accordance with N.J.A.C. 8:33-3.5(a)2	Exempt	Trauma service	Full
TERMINATION/DISCONTINUANCE OF LICENSED BEDS, SERVICES OR FACILITIES		Any other new health/medical care technologies that the Department identifies as having a Statewide or regional impact	Full
General hospital (all beds/services)	Full	CAPITAL IMPROVEMENTS AND RENOVATIONS TO HEALTH CARE FACILITIES	Exempt
General hospital (some beds/services)		REPLACEMENT OF EXISTING NON-BED RELATED HEALTH CARE FACILITY/SERVICE	Exempt
No access problems	Exempt	TRANSFER OF OWNERSHIP	
Access problems	Expedited	LICENSED FACILITY	
All other health care facilities	Exempt	General hospital	Full
NON-BED RELATED HEALTH CARE SERVICES/FACILITIES		All other	Exempt
NEW/EXPANSION		UNIMPLEMENTED CERTIFICATE OF NEED	
Ambulatory care	Exempt	Less than 10 percent transfer of stock	Expedited
Ambulatory surgery facility	Exempt	Limited partnership interests	Expedited
Birth center	Exempt	Membership of nonprofit corporations	Expedited
Bone marrow transplant/harvesting including stem cell	Full	Death of applicant	Expedited
Cardiac diagnostic services/invasive (catheterization)		Change in entity without change in principals	Expedited
New full service	Expedited	All other changes	Not Accepted
New or addition to low risk	Expedited	UNIMPLEMENTED CERTIFICATE OF NEED	
Addition of catheterization equipment to full service	Exempt	CHANGE IN COST in accordance with N.J.A.C. 8:33-3.9(a)	Exempt
Replacement of equipment	Exempt	CHANGE IN FINANCING	Exempt
Cardiac surgical service	Full	CHANGE IN SCOPE	
New	Full	Increase in beds/MME/services	
Addition of operating rooms to licensed cardiac surgery service	Exempt	Not subject to CN review	Exempt
Cardiac transplant service	Full	Subject to CN review	Not Accepted
Central service agency	Full	Decrease in beds/MME/services	Exempt
Comprehensive outpatient rehabilitation Facility	Exempt	CHANGE OF SITE	
Emergency medical service helicopter	Full	Within same county in accordance with N.J.A.C. 8:33-3.9(b)1,3	Exempt
Extracorporeal shock wave lithotripter (kidney and/or biliary)	Exempt	Within same planning region in accordance with N.J.A.C. 8:33-3.9(b)2,4	Expedited
Gamma knife	Exempt	EXTENSION OF TIME	Expedited
Hemodialysis and peritoneal dialysis	Exempt	CN = Certificate of Need	
Home health agency	Full	CPC = Community Perinatal Center	
Hyperbaric chamber	Exempt	MME = Major Moveable Equipment	
Kidney transplant service	Full	Amended by R.2002 d.243, effective August 5, 2002.	
Lung transplant service	Full	See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).	
Magnetic resonance imaging/nuclear magnetic resonance	Exempt		
Megavoltage radiation oncology/linear accelerator	Exempt		
Mobile intensive care or advanced life support service (new)	Full		

Deleted former Exhibits 2 and 4; recodified former Exhibits 2 and 3 as Exhibits 1 and 2; added new Exhibit 3.