CHAPTER 33

CERTIFICATE OF NEED: APPLICATION AND REVIEW PROCESS

Authority

N.J.S.A. 26:2H–1 et seq.

Source and Effective Date

R.1998 d.278, effective June 1, 1998.
See: 30 N.J.R. 1005(a), 30 N.J.R. 1991(a).
R.1998 d.303, effective June 15, 1998.
See: 30 N.J.R. 303(a), 30 N.J.R. 2270(b).

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 November 28, 2003.
See: 34 N.J.R. 458(a).

Chapter Historical Note

Chapter 33 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 Chapter 33 was repealed and a new Chapter 33, Certificate of Need: Application and Review, was adopted by R.1985 d.498, effective October 7, 1985.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 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Subchapters 1 through 4 were repealed and a new Subchapter 1, General Provisions; Subchapter 2, Applicability of Certificate of Need Requirements; Subchapter 3, Types of Certificate of Need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 Subchapter 6, Certificate of Need Moratorium, was repealed and a new Subchapter 6, Certificate of Need Exemptions, was adopted as new rules by R.1993 d.442, effective September 7, 1993.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. The balance of the chapter was adopted as new rules by R.1998 d.303, effective June 15, 1998. See: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

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, and the Health Care Reform Act, P.L. 1992, c.160. 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, 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 604
Health-Agriculture Building
John Fitch Plaza
Trenton, New Jersey 08625–0360
(609) 292–6552

(d) In addition to (a) through (c) above, before filing a certificate of need application, prospective applicants are encouraged to contact the local advisory board in the service area(s) in which their proposed health care service(s) or facility is planned to examine the relationship of the proposed project with the local advisory board's plans and appropriate regulations. If the proposed service area overlaps more than one planning region, the applicant should consult with each of the affected local advisory boards.

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

(a) It is the public policy of the State that hospital and related health care services of the highest quality, of demonstrated need, efficiently provided, properly utilized, and at a reasonable cost are of vital concern to the public health. As provided by N.J.S.A. 26:2H–1, in order to provide for the protection and promotion of the health of the inhabitants of the State, promote the financial solvency of hospitals and similar health care facilities and contain the rising cost of health care services, the Department shall have the central, comprehensive responsibility for the development and administration of the State's policy with respect to health planning, hospital and related health care services planning, and health care facility cost containment programs, as well as planning with all public and private institutions whether State, county or municipal, incorporated or not incorporated, serving principally as nursing or maternity homes, residential health care facilities, or as facilities for the prevention, diagnosis, or treatment of human disease, pain, injury, deformity or physical condition(s). All such institutions 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 economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of 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 possible economies and improvement in services to be anticipated from the operation of joint central services, the adequacy of financial resources and sources of present and future revenues, the availability of sufficient health personnel supply 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 the State Health Planning Board 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 appeal the decision to the Health Care Administration Board, in accordance with N.J.S.A. 26:2H–9.

(g) No decision shall be made by the Commissioner contrary to the recommendations of the State Health Planning Board concerning a certificate of need application or any other matter, unless the State Health Planning Board and the applicant shall have been granted the opportunity for a fair hearing in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

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 has been determined to be complete by the Department and has been entered into the applicable review cycle.

"Acute hemodialysis" means the rendering of dialysis to a non-end stage renal disease patient with previously life-supporting renal function who has sustained abrupt loss of kidney function. Recovery of kidney function is expected in such cases.

"Adult day health care facility" means a facility which is licensed by the Department of Health to provide preventive, diagnostic, therapeutic, and rehabilitative services under medical supervision to meet the needs of functionally impaired adult patients exclusively on an outpatient basis.

"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.

"Alternate family care" means a contractual arrangement between a client, an alternate caregiving family, and a sponsoring agency whereby no more than two individuals in need of long-term care receive room, board, and care in the private residence of a non-related family that has been trained to provide the necessary caregiving.

"Alternate family care program" means a program operated by a community-based agency such as a home health care agency which is responsible for recruiting, screening, training, and supervising alternate family caregivers, as well as matching patients with alternate family caregivers and monitoring their status within this arrangement.

"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.

"Ambulatory care facility" means a health care facility or a distinct part of a health care facility in which preventive, diagnostic, and treatment services are provided to persons who come to the facility to receive services and depart from the facility on the same day. An ambulatory care facility does not perform surgical cases.

"Ambulatory surgery facility" means a surgical facility in which ambulatory surgical cases are performed and which is licensed as an ambulatory surgery facility, separate and apart from any other facility license. (It may be physically connected to another licensed facility, such as a hospital, but is corporately and administratively distinct.)

"Ambulatory surgical case" and "same day surgical case" are synonymous terms for a surgical procedure performed on a patient in a surgical facility generally requiring anesthesia, with a facility-based post surgery period of at least one hour, and generally without the requirement of an overnight stay.

"Applicant" means an individual, a partnership, a corporation (including associations and joint-stock companies), 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 residence" means a facility which is licensed by the Department of Health 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.

"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.

"Birth center" means an ambulatory care facility or a distinct part of a health care facility which is separately licensed as an ambulatory care facility which provides routine prenatal and intrapartal care. These facilities provide care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth.

1. "Routine intrapartal care" means labor and delivery services not requiring operative obstetrics or cesarean sections. Birth centers shall establish formal letters of agreement with a Community Perinatal Center-Intermediate or higher level Community Perinatal Center and a Regional Perinatal Center for obstetric and pediatric consultation, referral and/or transport services. (See N.J.A.C. 8:43A–28.1.)

"Bloodless surgery" means the performance of surgery in an acute care 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.

"Capital-related operating costs" means costs pertaining to buildings, fixtures, and moveable equipment, including depreciation, interest, rent/lease and property taxes.

"Central service facility" means a health care facility, regulated by the Department of Health, providing essential administrative and clerical support service to two or more direct providers of health care services in a region and which may also include some direct provision of health care services.

"Change in cost" means any cost in excess of the total approved capital cost in the most recent certificate of need approval for the project.

"Change in financing" means an increase in financing related charges for the project or an increase in the annual interest rate for the financing.

"Change in project scope" is defined as a deviation from the approved certificate of need which results in a change in any one of, but not limited to, the following:

1. Number of beds by service;

2. Change in complement of major movable equipment;

3. Array of services;

4. Service area;

5. Access or availability to the approved project;

6. Population served including the percentage of Medicaid and medically indigent required to be served as a condition of certificate of need approval; or

7. Square footage.

"Change in the method of financing" means a change in the source of financing for a project (for example a change from tax-exempt bonds to taxable bonds), or a change in the amount of project costs which are to be paid from cash, fund raising, grants or other sources other than mortgages, loans or leases.

"Chronic renal dialysis facilities" means a facility in which dialysis is rendered to a patient with end stage renal disease for whom recovery of renal function is not expected.

"Commissioner" means the State Commissioner of Health.

"Community perinatal center" means a licensed hospital designated within a Maternal and Child Health Service Region as one of the following:

1. "Community perinatal center-basic" means a licensed general acute care hospital which provides services to uncomplicated maternity and normal newborn patients in accordance with the scope of functions delineated in its formal letter of agreement with the regional perinatal center. This hospital is characterized by physically separated facilities for labor, delivery, and newborn care, with cesarean section capability within the perinatal suite. The hospital must also provide supportive care for infants returned from regional or community perinatal center-intensive care facilities. Such a facility shall provide care to patients expected to deliver neonates greater than 2,499 grams and at least 36 weeks gestational age.

2. "Community perinatal center-intermediate" means a licensed general acute care hospital which provides care to a minimum of 800 complicated maternity patients and neonates in accordance with the scope of functions delineated in its formal letter of agreement with the regional perinatal center. Such a facility shall provide care to patients expected to deliver neonates greater than 1,499 grams and at least 32 weeks gestational age.

3. "Community perinatal center-intensive" means a licensed general acute care hospital which provides care to complicated maternity patients and neonates in accordance with the scope of functions delineated in its letter of agreement with the hospital and the Regional Perinatal Center. Such a facility shall provide care to patients expected to deliver neonates greater than 999 grams and at least 28 weeks gestational age.

"Community-based primary care center" means a health care facility which provides preventive, diagnostic, treatment, management and reassessment services to individuals with acute or chronic illness exclusively on an outpatient basis. The term is used in reference to facilities providing family practice, general internal medicine, general pediatrics, obstetrics, gynecology, and/or clinical preventive services, including community health centers providing comprehensive primary care and/or reproductive health services, including abortions. Comprehensive primary care may include the provision of sick and well care to all age groups, from perinatal and pediatric care to geriatric care. For the purposes of this chapter, services identified in the Appendix, Exhibit 2, incorporated herein by reference are not community-based primary care services and, therefore, are subject to the certificate of need requirement.

"Comprehensive personal care home" means a facility which is licensed by the Department of Health to provide room and board and to assure that assisted living services are available when needed, to four or more adults unrelated to the proprietor. Residential units in comprehensive personal care homes house no more than two residents and have a lockable door on the unit entrance.

"Construction" means the erection, building, alteration, reconstruction, improvement, renovation, extension or modification of a health care facility, including fixed equipment, the inspection and supervision thereof; and the studies, surveys, designs, plans, working drawings, specifications, procedures, and other actions necessary thereto.

"Construction cost factor" means the inflation factor calculated by the Department and added to the certificate of need approved total project cost. This construction cost factor is calculated as a factor of the time between certificate of need submission and initiation of construction, and is based on a standardized industry measurement of construction cost inflation.

"Continuing care retirement community" means the provision of lodging and nursing, medical or other health related services at the same or another location to an individual pursuant to an agreement effective for the life of the individual or for a period greater than one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without other periodic charges. A fee which is less than the sum of the regular periodic charges for one year of residency is not considered an entrance fee.

"Deferral" means a suspension of the review of a submitted application for a limited period of time.

"Demonstration/research project" generally refers to a health care service, technology, equipment or modality not currently available in the State. A demonstration project requires a certificate of need as specified at N.J.A.C. 8:33–3.11. The services provided through a demonstration project are not generally available in the State; consequently, the demonstration project does not compete with or affect other health care providers in the State. For purposes of this chapter, "demonstration projects" are distinguishable from "research projects" in that technologies offered as demonstrations have pre-market approval from the United States Food and Drug Administration and are not considered investigational or experimental; services provided through demonstration projects may be billed for and receive reimbursement from patient and third party billings; the recipients of services provided at a demonstration are not limited to the subjects of research, as is the case with "research projects," (See also the definition of "research project" below, as well as N.J.A.C. 8:33–3.11 concerning demonstration and research projects.)

"Department" means the New Jersey State Department of Health.

"Direct review process" means the review, in accordance with the requirements of this chapter, of an application by the Department of Health and State Health Planning Board of a certificate of need application meeting certain specified criteria in accordance with a Statewide need determination. Such a review process does not include a review by the local advisory board.

"Discontinuance" means any health care facility which has closed or substantially ceased operation of any of its beds, facilities, services, or equipment for a period of two succeeding years.

"Emergency medical service helicopter" means a service which provides aeromedical emergency care and transportation by rotowing aircraft and is licensed in accordance with N.J.A.C. 8:41.

"Equipment system" means a group of equipment units, which operate together to perform a function. For example, the central processing unit of a computer and its peripheral equipment comprise an equipment system. The bedside cardiac monitor units and the nursing console form an equipment system.

"Equipment unit" is an apparatus that can perform its designated function by itself without the addition of any other component.

"Expedited review process" means the review by the Department of Health of a certificate of need application meeting certain specified criteria. Such a review process does not include a review by the local advisory board or the Statewide Health Planning Board.

"Financing charges" means charges, fees and costs incurred by a health care facility in connection with obtaining financing for a project, including, but not limited to: points, discount, financing fees and other charges by the financing agency, authority, bank or trustee; interest on borrowings during construction, net of any interest earnings derived from the investment of borrowed funds; fees of bond counsel, counsel to the lender and counsel to the trustee, if any; fees of accountants and feasibility or other financial consultants; a reserve for debt service equal to one year's principal and interest; charges for title insurance, mortgage insurance, bond insurance or other insurance required in connection with the financing; and rating service fees, printing costs and other costs incurred in connection with the financing; provided that where financing is being provided with tax exempt bonds, an application for a certificate of need will be deemed to include a reserve for debt service of one year's principal and interest and a reasonable underwriter's discount or financing fee, as approved by the bond issuing authority.

"Fixed equipment" means equipment which is attached to the physical plant of a facility.

"Full review process" means the review of an application by the local advisory board(s) and the Statewide Health Planning Board, as well as the Department of Health.

"Health care facility" means the facility or institution, whether public or ~~private,~~ engaged principally in providing services for health maintenance organizations, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, intermediate care facility, assisted living residence, comprehensive personal care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, residential health care facility and bioanalytical laboratories (except as specifically excluded hereunder) or central services facility serving one or more such institutions but excluding institutions that provide healing solely by prayer and excluding such bioanalytical laboratories as are independently owned and operated, and are not owned, operated, managed or controlled in whole or in part, directly or indirectly by any one or more health care facilities and the predominant source of business of which is not by contract with health care facilities within the State of New Jersey and which solicit or accept specimens and operate predominantly in interstate commerce.

"Health care service" means the preadmission, outpatient, inpatient, and postdischarge care provided in or by a health care facility, and such other items or service as are necessary for such care, which are provided by or under the supervision of a physician for the purpose of health maintenance or diagnosis or treatment of human disease, pain, injury, disability, deformity, or physical condition, including, but not limited to, nursing service, home care nursing and other paramedical service, ambulance service, service provided by an intern, resident in training or physician whose compensation is provided through agreement with a health care facility, laboratory service, medical social service, drugs, biologicals, supplies, appliances, equipment, bed and board, but excluding services provided by a physician, nurse practitioner, clinical nurse specialist, certified nurse midwife or physician assistant, in his or her private practice, unless the service is the subject of a health planning regulation as defined in this section, adopted by the Department of Health or involves the acquisition of major moveable equipment as specified herein, and services provided by volunteer first aid, rescue and ambulance squads as defined in the New Jersey Highway Safety Act of 1971, P.L. 1971, c.351.

"Health maintenance organization" or "HMO" means an entity which has received a certificate of authority to provide prepaid health care services pursuant to the Health Maintenance Organizations Act, P.L. 1973, c.337 (N.J.S.A. 26:2J–1 et seq.) inclusive of any amendments which may be made thereto.

"Invalid coach service" means the provision of non-emergency health care transportation, by certified personnel, for sick, infirm or otherwise disabled persons who are under the care and supervision of a physician and whose medical condition is not of sufficient magnitude or gravity to require transportation by ambulance, but does require transportation from place to place for medical care, and whose use of an alternate form of transportation, such as taxicab, bus, other public conveyance or private vehicle, may create a serious risk to life and health.

"Local advisory board" means an independent, private non-profit corporation established pursuant to N.J.S.A. 26:2H–5.9, which is not a health care facility, a subsidiary thereof or an affiliated corporation of a health care facility, that is designated by the Commissioner of Health to serve as the regional health planning agency for a designated region in the State.

"Major moveable equipment" means equipment, including installation and renovation, which is the subject of a health planning regulation or which is proposed by the Commissioner to be the subject of a health planning regulation as defined in this section. For purposes of this chapter, major moveable equipment shall include all equipment which receives pre-marketing approval from the U.S. Food and Drug Administration unless the Health Care Administration Board explicitly excludes a specific piece of equipment or a specific technology from the classification of major moveable equipment. Examples of major moveable equipment are identified in the chapter Appendix, Exhibit 3, incorporated herein by reference.

"Mandatory replacement of equipment and/or mandatory renovations to facilities" means replacement of equipment or renovation for one or more of the following reasons:

1. Replacement or renovation is required as a result of a mandate from any Federal, State, county or municipal governmental agency; or

2. Replacement or renovation is required to operate the licensed health care facility without harm or major disruption to the care of patients or to the health and safety of patients, providers, or employees of the health care facility. Examples of this type of replacement would include a breakdown of a heating and/or cooling plant within a facility or a malfunction rendering inoperable the power plant of a facility.

"Medical arts building" or "medical office building" means a building whose primary function is to provide office space for a person or persons engaged in the private practice of medicine.

"Medically underserved" means segments of the population whose utilization of health care services is less than those numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services. Medically underserved includes, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"Minor moveable equipment" means equipment which does not fall within the definition of major moveable equipment stated herein.

"Mobile intensive care unit" (MICU) means a specialized emergency medical service vehicle staffed by mobile intensive care paramedics or mobile intensive care nurses trained in advanced life support nursing and operated for the provision of advanced life support services under the direction of an authorized hospital.

"Modernization/renovation" means the alteration, expansion, major repair, remodeling, replacement, and renovation of existing buildings, and the replacement of obsolete equipment of existing buildings.

"Nonbed related outpatient psychiatric care" means the following, which, to be considered a health care service must meet standards as prescribed by the rules and regulations governing community mental health services and State aid under the Community Mental Health Services Act (N.J.A.C. 10:37):

1. Outpatient psychiatric care: Mental health services provided in a community setting to clients who possess a psychiatric diagnosis, including clients who are seriously and persistently mentally ill but excluding substance abuse and developmental disability unless accompanied by treatable symptoms of mental illness. Periodic therapy, counseling, and supportive services are generally provided onsite at the provider agency for relatively brief sessions (between 30 minutes and two hours). Services may be provided individually, in group, or in family sessions.

2. Partial psychiatric care: A mental health program which provides several hours of program involvement to maximize client's independence and community living skills. Efforts are also made to reduce unnecessary hospitalization. Partial care programs provide or arrange for a full range of services necessary to meet the comprehensive needs of individual needs;

3. Emergency psychiatric services: The provision of 24 hour, seven day a week service to people in crisis. Emergency services offer intermediate crisis intervention and service procurement to relieve the client's distress and to help maintain or restore his/her level of functioning in the least restrictive setting.

4. Designated psychiatric screening center: A public or private ambulatory care service designated by the Commissioner of Human Services, which provides mental health services including assessment, screening, emergency and referral services to mentally ill persons in a specified geographic area. A designated screening center is the facility in the public mental health care treatment system wherein a person believed to be in need of commitment to a short-term care, psychiatric facility or special psychiatric hospitals undergoes an assessment to determine what mental health services are appropriate for the person and where those services may be appropriately provided.

"Null and void," "nullification," and "nullify" means the revocation of a certificate of need by the Commissioner prior to the expiration of the certificate.

"Operating revenues" means total operating revenues from the hospital's most recent year audited financial statements, which will be inflated using a global economic factor, as defined in N.J.A.C. 8:31B, which measures the change in

the prices of goods and services used by New Jersey hospitals.

"Operating room" means a room specifically dedicated to the performance of surgical cases which meets the State Uniform Construction Code, at N.J.A.C. 5:23–3 and the Department's licensing requirements. For purposes of this definition, rooms specifically dedicated to endoscopic and cystoscopic procedures are not considered operating rooms.

"Operator" of a health care facility means the person or entity which is the holder of the facility license and which has the ultimate responsibility for the provision of health care services in the facility in accordance with applicable legal and professional standards.

"Optional replacement of equipment" means replacement equipment which will perform more analyses, operate more efficiently, economically or reliably or in some manner improve operations in a unit, but which maintains existing capability and does not include upgrading to a newer technology that expands the range of service.

"Outpatient alcoholism service" means the provision of scheduled, or non-scheduled, non-residential diagnostic and primary alcoholism treatment services.

"Outpatient drug service" means the provision of non-residential drug abuse treatment modalities, including methadone maintenance, drug free outpatient and day care services.

"Pediatric day health care facilities" means a facility which is licensed by the Department of Health to provide preventive, diagnostic, therapeutic, and rehabilitative services under medical supervision to meet the needs of chronically ill and medically fragile children exclusively on an outpatient basis.

"Pediatric service" means provision of services by a general acute care hospital to pediatric patients.

"Person" shall include a corporation, company, association, society, firm, partnership and joint stock company, as well as an individual.

"Postanesthesia care unit" means a room, or area, used for post-anesthesia recovery of patients which meets the State Uniform Construction Code, at N.J.A.C. 5:23–3 and the Department's licensing requirements.

"Principal" means any individual, partnership, or corporation with an ownership interest in a health care facility or service, or a general or managing partner in a limited partnership.

"Project" means the compilation, during a single calendar year, of architectural, engineering and/or construction services for renovation provided by individuals or firms which are not employees of the hospital and for which financing is required to fund the project. If the hospital incurs capital expenditures without use of the external services as described above, then each planned renovation of any discrete area or unit of the hospital shall be considered a separate project.

"Project cost" means costs submitted in those dollars which would be needed to complete the project over the anticipated period of construction, if construction were to begin at the time of certificate of need submission.

"Provider of health care" means an individual:

1. Who is a direct provider of health care service in that the individual's primary activity is the provision of health care services to individuals or the administration of health care facilities in which such care is provided and, when required by State law, the individual has received professional training in the provision of such services or in such administration; or

2. Who is an indirect provider of health care in that the individual:

i. Holds a fiduciary position with, or has a fiduciary interest in, any entity described in subparagraph 2ii(2) or subparagraph 2ii(4) below; provided, however, that a member of the governing body of a county or any elected official shall not be deemed to be a provider of health care unless he is a member of the board of trustees of a health care facility or a member of a board, committee or body with authority similar to that of a board of trustees, or unless he participates in the direct administration of a health care facility; or

ii. Received, either directly or through his or her spouse, more than one-tenth of his or her gross annual income for any one or more of the following:

(1) Fees or other compensation for research into or instruction in the provision of health care services;

(2) Entities engaged in the provision of health care services or in research or instruction in the provision of health care services;

(3) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research into or instruction in the provision of health care services; or

(4) Entities engaged in producing drugs or such other articles.

"Purchase cost" means the cost of acquisition of a single unit of fixed or major moveable equipment including installation and renovation.

"Regional perinatal center" means a licensed general acute care hospital designated within a Maternal and Child Health Service Region which is required to provide care to high risk mothers and neonates. Such a facility shall provide consultation, referral, transport and consultation to its regional affiliates.

"Research projects" are projects whose scope of inquiry and activity are exclusively limited to the execution of a research protocol which when it involves human subjects must be approved by an Institutional Review Board; whose services and interventions are provided to approved study subjects alone; who do not bill for or receive reimbursement for the services, equipment, or interventions provided through the research; and whose services, equipment, or interventions are not competing with and do not negatively impact upon licensed providers of health care services in the State, as determined by the Commissioner of Health. (See also the definition of "demonstration project" above and N.J.A.C. 8:33–3.11.)

"Residential health care facility" means a facility which provides food, shelter, supervised health care and related services to four or more persons 18 years of age or older who are unrelated to the owner or administrator.

"Same day surgical case" and "ambulatory surgical case" are synonymous terms for a surgical procedure performed on a patient in a surgical facility generally requiring anesthesia, with a facility-based post surgery period of at least one hour and without the requirement of an overnight stay.

"Satellite" means a community-based primary care center which is an affiliate of a separately licensed ambulatory care facility. A satellite is located at a site distinct from that of the separately licensed ambulatory care facility, but shares the same governing authority and provides the same principal service as the separately licensed ambulatory care facility.

"Service area" means a geographic area, generally a county, within which the facility or service is located. However, definitions of service areas specified in approved planning rules shall take precedence over this general definition.

"Similar equipment units" means pieces of equipment which are similar in function and appearance. For example, a manually operated bed and an electrically operated bed are similar units. A 1,000 power microscope and 500 power microscope are similar units. A coulter counter and a microscope are not similar units.

"Special child health clinic" means a clinic staffed by multi-disciplinary teams (as specified by Special Child Health Services Criteria) having expertise in evaluation and medical management of children with low incidence conditions. The team will include and be under the medical direction of pediatric sub-specialists appropriate to the population served (for example, cleft lip/palate, sickle cell).

"State Health Planning Board" means the board established pursuant to N.J.S.A. 26:2H–5.7, to prepare and review the State Health Plan and to conduct certificate of need review activities.

"Statewide restricted admissions facility" means a nonprofit nursing home owned and operated by a religious or fraternal organization that serves only members of that organization and their immediate families and meets the specific requirements set forth in N.J.A.C. 8:33H.

"Subject of a health planning regulation" means any health care service identified in the Appendix, Exhibit 2.

"Surgical facility" means a structure or suite of rooms which has the following characteristics:

1. At least two rooms dedicated for use as operating rooms which are specifically equipped to perform surgery. These rooms are designed and constructed to accommodate invasive diagnostic and surgical procedures; and

2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged.

"Surgical practice" means a structure or suite of rooms which has the following characteristics:

1. One room dedicated for use as an operating room which is specifically equipped to perform surgery. This room is designed and constructed to accommodate invasive diagnostic and surgical procedures;

2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and

3. Established by a physician or physician professional association surgical practice solely for his/her/their private medical practice.

"Termination" means a certificate of need is not extended by the Commissioner beyond its expiration date.

"Total capital cost" means all costs associated with the proposed project including studies and/or surveys; architect, engineer, legal fees; plans and specifications; supervision and inspection of site and buildings; demolition, renovation, construction; fixed and major moveable equipment, purchase of land and buildings; lease and/or rentals; developmental and/or start up costs, but excluding carrying and financing cost and/or fees, interest and debt service reserve fund. Total capital cost excludes any contingency amounts.

"Total project cost" means all costs associated with the proposed project, including all capital costs, carrying and financing costs, net interest on borrowings during construction, debt service reserve fund. Total project cost excludes any contingency amounts.

"Withdrawal" means a voluntary written request by a certificate of need applicant to the Department to cease any further review of a submitted application submitted before the Commissioner acts on the application. Such a request shall be considered final by the Department and no further consideration or review shall be given to the "withdrawn" application.

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.1999 d.272, effective August 16, 1999.
See: 31 N.J.R. 950(a), 31 N.J.R. 2375(a).
Inserted "Bloodless surgery".

Case Notes

Certificate of need required when private physician initiated health care service. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Determination that certificate of need was not required, remand required for specific findings of fact. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Standing to appeal determination on application for certificate of need. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Commissioner did not have discretion to remove condition in certificate of need for linear accelerator. In re Certificate of Need Application of Chilton Memorial Hosp., 269 N.J.Super. 426, 635 A.2d 986 (A.D.1993).

Policy statement illustrates pervasiveness of State's regulatory concern. Desai v. St. Barnabas Medical Center, 103 N.J. 79, 510 A.2d 662 (1986).

SUBCHAPTER 2. APPLICABILITY OF CERTIFICATE OF NEED REQUIREMENTS

8:33–2.1 Types of review

There will be three types of review of certificate of need applications: full review, as described in N.J.A.C. 8:33–4.1(a), direct review, as described in N.J.A.C. 8:33–4.1(b), and expedited review, as described in N.J.A.C. 8:33–4.1(c). The full review process shall apply to all certificate of need applications not specifically identified herein as meeting the criteria for direct review or expedited review. The review process shall apply as specified in Exhibit 4 of the Appendix, incorporated herein by reference.

Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

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).

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 A.2d 662 (1986).

8:33–2.2 Determination of a health care facility or service

(a) It is incumbent upon all health care facilities and services to comply with the certificate of need requirements set forth in statute and rules promulgated pursuant thereto. If such automatic compliance is not forthcoming, the Commissioner, consistent with the "public policy of the State that hospital and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost are of vital concern to the public health" (N.J.S.A. 26:2H–1) and in accordance with the definitions of a health care facility and a health care service, as specified in N.J.S.A. 26:2H–2 and 26:2H–7, shall determine whether a proposed or existing system or modality of health care delivery constitutes a health care service or health care facility subject to certificate of nee requirements. If so designated, such facility shall be subject to all of the provisions of the Health Care Facilities Planning Act (N.J.S.A. 26:2H–1 et seq.) and rules promulgated pursuant thereto.

(b) In making this determination, the Commissioner may choose to request the advice and comment of the State Health Planning Board and/or the local advisory board within whose boundaries the proposed or existing health care modality in question originates.

(c) Those factors which shall be considered relevant to the determination of a health care facility or service shall include:

1. The types of health care service and facilities, and changes thereto, which are required to obtain certificate of need approval by the provisions of this subchapter;

2. The type of health care service delivered or to be delivered, its impact on existing health care facilities and providers and its potential effect on the health care delivery system;

3. The apparent costs of equipping, staffing and operating the health care service and the resultant cost to all payors and consumers of health care;

4. The degree of complexity in terms of medical technology, equipment, and the medical, paramedical and administrative staffing required to provide the health care service;

5. The evaluation of how historically established referral patterns will be impacted upon by the proposed service;

6. The financial arrangements for the payment or reimbursement of health care services available to both the service entity in question and to those persons receiving such care; and

7. Any other factors specific to the unique circumstances of an individual applicant.

(d) When a determination is made that a health care service/health care facility is deemed to require certificate of need review, the person(s) involved shall be so notified by the Commissioner. The Commissioner's decision shall be a final agency decision.

Law Review and Journal Commentaries

Health Law—Hospitals. Steven P. Bann, 136 N.J.L.J. No. 5, 66 (1994).

Case Notes

Commissioner could not have discretion to remove condition in certificate of need for linear accelerator. In re Certificate of Need Application of Chilton Memorial Hosp., 269 N.J.Super. 426, 635 A.2d 986 (A.D.1993).

Women's medical centers held by Commissioner to be health care facilities; Appellate Division held that regulations cannot apply to private office on basis of internal business management. Women's Medical Center at Howell v. Finley, 7 N.J.A.R. 262 (1982), reversed 192 N.J.Super. 44, 469 A.2d 65, certification denied 96 N.J. 279, 475 A.2d 578. (App.Div.1983).

Outpatient drug rehabilitation clinic required to obtain certificate of need; zoning ordinance liberally construed to permit clinic operation. L & L Clinics, Inc. v. Irvington, 189 N.J.Super. 332, 460 A2d 152 (App.Div.1983), certification denied 94 N.J. 540, 468 A.2d 191 (1983).

Statutory amendment exempting certain non-profit corporations from certificate of need requirements constitutional; amendment not prohibited special legislation. Paul Kimball Hospital v. Brick Twp. Hospital, 86 N.J. 429, 432 A.2d 36 (1981).

Mobile multiphasic health testing service is a health care facility subject to certificate of need requirements. Medcor, Inc. v. Finley, 179 N.J.Super. 142, 430 A.2d 964 (App.Div.1981).

Denial of medical center's application for certificate of need could not be reviewed for reasonableness in absence of a specific articulation in record of reasons for denial. In Re Hunterdon Application, 95 N.J.A.R.2d (HLT) 11.

Improper transfer of nursing care facilities; period from dates on which facilities entered into agreements until applications for Certificate of Need filed constituted periods of violations; penalties assessed. In Matter of Oakridge Manor Nursing Home. 93 N.J.A.R.2d (HLT) 1.

Denial of Certificate of Need for proposed hyperbaric chamber facility; reasonable. New Jersey Chamber Facility, Inc. v. Department of Health. 92 N.J.A.R.2d (HLT) 5.

Failure to secure legal representation to appeal decision approving application for certificate of need for development of a Hyperbaric Oxygen Therapy Program warranted dismissal of appeal. N.J.S.A. 26:2H–6. In Matter of the Medical Center of Ocean County, 91 N.J.A.R.2d 1 (HLT).

Appeal from denial of certificate of need; reimbursement for construction costs which exceeded the approved project cost denied as untimely; denial of reimbursement for petitioner's interest amortization rate. Hillcrest Manor v. Dep't of Human Services, 9 N.J.A.R. 45 (1983).

Religiously sponsored nursing homes not exempt from certificate of need requirements; religious need another factor in certificate determination. Attorney General Formal Opinion 1974–No. 2.

8:33–2.3 Waivers to certificate of need requirements for physicians

(a) A physician who initiates a health care service which is the subject of a health planning regulation, as defined at N.J.A.C. 8:33–1.3, or purchases major moveable equipment whose total cost is over $1,000,000, is subject to the certificate of need requirement. However, a physician may apply to the Commissioner for a waiver of the certificate of need requirement.

(b) The application by a physician for a waiver of the certificate of need requirement shall be considered pursuant to the following criteria:

1. The equipment or health care service is such an essential, fundamental and integral component of the physician's practical specialty, that the physician would be unable to practice his or her specialty according to the acceptable medical standards of that specialty without the health care service or equipment;

2. The physician bills at least 75 percent of his or her total amount of charges in the practice specialty which uses the health care or equipment; and

3. The health care service or equipment is not otherwise available and accessible to patients pursuant to standards identified in the specific health planning rules guiding the review of the proposed service or equipment. However, where these standards are not identified in relevant health planning regulations, a physician may satisfy this criteria by documenting to the satisfaction of the Commissioner, that the proposed service or equipment is not otherwise available or accessible for geographic, financial or other reasons to patients at a health care facility which has received certificate of need approval for the health care service or equipment within 30 minutes travel time of the physician's proposed site for the planned service or equipment.

(c) The physician's documentation in support of his or her petition for a waiver shall include, but may not be limited to, a detailed description of the service or equipment, a statement of the costs related to the implementation, a detailed explanation of patients to be served, detailed assessment of the costs, risks and benefits to patients and an assessment of the impact that the subject of the petition will have on the health care delivery system in general, and on the specific providers of that service in the area in which the service will be located. The Commissioner may make inquiries of existing providers in the area proposed to be served to determine the impact of those providers. In addition, the physician shall identify how his or her service will provide access to persons who are unable to pay the full cost of care and how the service will advance P.L. 1991, c.187 in regard to access, quality and cost containment.

(d) The satisfaction of (b)1, 2, and 3 above shall be judged according to the following standards:

1. In assessing a physician's petition for a waiver of the certificate of need requirements, the Commissioner shall be guided by the principles set forth in P.L. 1991, c.187.

2. The certificate of need requirement shall not be waived for any health care service proposed to be provided by a physician to inpatients.

3. The certificate of need requirement shall not be waived for any diagnostic or therapeutic health care service proposed to be offered by a physician in an outpatient setting when the Commissioner finds that the service as proposed represents an unnecessary risk to patients (for example, services that can only be offered, by Department regulation, in acute care settings with appropriate backup).

4. A petition for a waiver may not be made concurrently with the submission by the physician seeking the waiver of a certificate of need application for the service. If such an application has been submitted, it shall be deferred automatically into the first available batch following a determination on the waiver.

(e) The Commissioner shall make a determination about whether to grant or deny the waiver based upon the criteria set forth at (b)1 through 3 above within 120 days from the date the request for the waiver is received by the Commis-

sioner and shall so notify the physician who requested the waiver. If the request is denied, the Commissioner shall include in that notification the reason for denial of the waiver. If the request is denied, the proposed health care service or the proposed acquisition of major moveable equipment shall be subject to certificate of need requirements pursuant to this chapter. The Commissioner's determination whether to grant or deny the waiver shall be a final agency decision.

Amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Case Notes

Certificate of need required when private physician initiated health care service. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Determination that certificate of need was not required, remand required for specific findings of fact. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Standing to appeal determination on application for certificate of need. Associates In Radiation Oncology, P.A. v. Siegel, 272 N.J.Super. 208, 639 A.2d 729 (A.D.1994).

Acting Commissioner did not have discretion to remove condition in certificate of need for linear accelerator. In re Certificate of Need Application of Chilton Memorial Hosp., 269 N.J.Super. 426, 635 A.2d 986 (A.D.1993).

Requirement of certificate of need prior to acquisition of major medical equipment valid; policy statement applying regulation to providers of CT scanner and MRI services not rulemaking but application of existing regulation. Radiological Society of New Jersey v. New Jersey State Dept. of Health, 208 N.J.Super. 548, 506 A.2d 755 (App. Div.1986), certification denied 104 N.J. 444, 517 A.2d 434.

Proposed purchase of C.A.T. scanner by private physician does not constitute operation of health care facility subject to certificate of need requirements; agency determination exceeds legislative intent. Marsh v. Finley, 160 N.J.Super. 193, 389 A.2d 490 (App.Div.1978), certification denied 78 N.J. 396, 396 A.2d 583. (1978).

8:33–2.4 Waivers to certificate of need requirements for health maintenance organizations

(a) A health maintenance organization which furnishes at least basic comprehensive care health services on a prepaid basis to enrollees either through providers employed by the health maintenance organization or through a medical group or groups which contract directly with the health maintenance organization may apply to the Commissioner for a waiver of certificate of need requirements for:

1. The initiation of any health care service as provided in section 2 of P.L. 1971, c.136 (N.J.S.A. 26:2H–2);

2. The initiation by any person of a health care service which is the subject of a health planning regulation adopted by the Department as defined at N.J.A.C. 8:33–1.3;

3. The expenditure by a licensed health care facility of over $1,000,000 for modernization or renovation of its physical plant, or for construction of a new health care facility; or

4. The modernization, renovation or construction of a facility by any person, whose total project cost exceeds $1,000,000, if the facility-type is the subject of a health planning regulation as defined at N.J.A.C. 8:33–1.3.

(b) The application by a health maintenance organization for a waiver of the certificate of need requirements may be made if the following criteria are met:

1. The initiation of the health care service or the modernization, renovation or construction is in the best interests of State health planning; and

2. The health maintenance organization is in compliance with the provisions of P.L. 1973, c.337 (N.J.S.A. 26:2J–1 et seq.) and complies with the provisions of subsection d of section 3 of P.L. 1973, c.337 (N.J.S.A. 26:2J–3) regarding notification to the Commissioner.

(c) In its petition for a waiver, the health maintenance organization shall provide sufficient information, which shall include, but need not be limited to, a detailed description of the service or equipment, statement of the costs related to the implementation, detailed explanation of patients to be served, detailed assessment of the costs, risks and benefits to patients and an assessment of the impact that the subject of the petition will have on the health care delivery system in general, and on the specific providers in the area in particular. The Commissioner may make inquiries of existing providers in the area proposed to be served to determine the impact on those providers.

(d) The satisfaction of (b)1 and 2 above shall be judged according to the following standards:

1. In assessing a health maintenance organization's petition for a waiver of the certificate of need requirements, the Commissioner shall be guided by the principles set forth in P.L. 1991, c.187.

2. The certificate of need requirement shall not be waived for any health care service proposed to be provided by a health maintenance organization to inpatients.

3. The certificate of need requirement shall not be waived for any diagnostic or therapeutic health care service proposed to be offered by a health maintenance organization in an outpatient setting where the Commissioner finds that the service as proposed represents an unnecessary risk to patients (for example, services that can only be offered by Department regulation in acute care settings with appropriate backup).

4. A petition for a waiver may not be made concurrently with the submission by the health maintenance organization seeking the waiver of a certificate of need application for the service. If such an application has been submitted, it shall be deferred automatically into the first available batch following a determination on the waiver.

(e) The Commissioner shall make a determination about whether to grant or deny the waiver within 45 days from the date the request for the waiver is received by the Commissioner and shall so notify the health maintenance organization requesting the waiver. If the request is denied, the Commissioner shall include in that notification the reason for denial of the waiver. If the request is denied, the proposed health care service or the proposed acquisition of major moveable equipment shall be subject to certificate of need requirements pursuant to this chapter. The Commissioner's determination whether to grant or deny the waiver shall be a final agency decision.

Amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

Case Notes

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.

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 2, 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 stated in 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).

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, services, or equipment for any consecutive two-year period shall be required to obtain a certificate of need before reopening such beds, facilities, services, or equipment.

(b) The Commissioner may amend a facility's license to reduce that facility's licensed bed capacity to reflect actual utilization at the facility if the Commissioner determines that 10 or more licensed beds in the health care facility have not been used for any consecutive two-year period. For the purposes of this subsection, the Commissioner may retroactively review utilization at a facility for any two-year period beginning on or after January 1, 1990.

(c) 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 acute care hospital requires a certificate of need and shall follow the full review process. Applications for the closure of a general acute care 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, 120 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.

(d) Discontinuance of a component service of a health care facility 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. The Department will notify the provider whether the proposed discontinuance requires a certificate of need which shall follow the expedited review process set forth at N.J.A.C. 8:33–4.1(c).

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).

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 acute care 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;

2. A transfer which will result in a new 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);

3. Acute care beds, services or equipment owned and/or operated by an acute care hospital. The corporate unbundling of acute care beds, services or equipment identified in the Appendix, Exhibit 2, owned and/or operated by an acute care hospital shall require a certificate of need. Corporate unbundling refers to the transfer of ownership of acute care beds, services or equipment

owned or operated by an acute care hospital and the establishment of that service under a new corporation and under a separate license from the acute care hospital's license. Applications for such shall follow the expedited review process set forth at N.J.A.C. 8:33–4.1(c);

4. A long-term care facility in which the proposed owner does not satisfy the Department's review of the proposed owner's prior operating experience in accordance with the criteria identified in this chapter and N.J.A.C. 8:33H, as well as any requirements established by the Federal government pursuant to Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 483.1 through 483.158. Applications shall follow the expedited review process set forth at N.J.A.C. 8:33–4.1(c).

5. A physician who initiates a service pursuant to the grandfathering provisions of P.L. 1992, c.160, N.J.S.A. 26:2H–7, may not transfer the service without going through the certificate of need process, and except as provided for at N.J.A.C. 8:33–3.7(a)2, shall follow the expedited review process set forth at N.J.A.C. 8:33–4.1(c); and

6. The waivered status of a service is not transferable. A physician or health maintenance organization who initiates a service pursuant to the waiver provisions of P.L. 1991, c.160, N.J.S.A. 26:2H–7, may not transfer the service without approval of a waiver from the certificate of need requirements in accordance with N.J.A.C. 8:33–2.3 and 2.4 prior to the transfer. Upon approval of a waiver, application for a license shall be made in accordance with (b) below. If the application for waiver is denied, the service may not be transferred without going through the certificate of need process and 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 subsequent to licensure, 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, 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;

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 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. The Commissioner shall seek the recommendation of the State Health Planning Board and the State Health Planning Board may seek the recommendation of the local advisory board. The State Health Planning Board may appeal a decision of the Commissioner which is contrary to its recommendation (see N.J.A.C. 8:33–4.15).

(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).

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 and shall follow the full review or direct review process, except as provided for at N.J.A.C. 8:33–5, 8:33–6 and as follows:

i. 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 shall not require a certificate of need, but shall apply to the Department's Long-Term Care Licensing and Certification Program for authorization pursuant to N.J.S.A. 26:2H–7.2.

ii. An increase in the bed complement of an existing licensed residential health care facility shall not require a certificate of need.

iii. An acute care hospital proposing to increase its total number of licensed medical/surgical beds by no more than 20 percent of its licensed medical/surgical bed capacity within a period of five years shall not require a certificate of need.

iv. An acute care hospital proposing to increase its total number of licensed ob/gyn, pediatric (excluding pediatric intensive or critical care), or adult ICU/CCU beds by no more than 10 beds or 20 percent of its licensed capacity in the licensure bed category, whichever is less, within a period of five years shall not require a certificate of need.

v. Total project costs exclusively associated with the bed increases identified at (a)1i through iv above shall be exempt from the certificate of need requirement. The applicant shall submit to the Department, prior to building construction or renovation, supporting contract documentation with certification from the architect and/or contractor which verifies the total project cost for the bed increase for the review and approval of the New Jersey Department of Community Affairs. The approval of the New Jersey Department of Community Affairs will be based upon the State Uniform Construction Code, N.J.A.C. 5:23–3 and the Department's licensing regulations.

vi. Establishment of a residential health care facility requires a certificate of need and shall follow the expedited review process set forth at N.J.A.C. 8:33–4.1(c).

2. Any decrease in the number of licensed beds by licensure and/or health planning category requires a certificate of need and shall follow the full review process, where the reduction in the licensed beds shall result in a capital expenditure greater than the monetary threshold specified in N.J.A.C. 8:33–3.6 or where the bed reduction would violate a condition of certificate of need approval imposed upon the provider, as determined by the Commissioner. A certificate of need shall not be required for any decrease in the number of licensed beds by licensure and health planning category where the reduction can be accomplished at a total capital expenditure less than the monetary threshold specified in N.J.A.C. 8:33–3.6 and where the reduction shall not violate a condition of approval of a certificate of need provided to or on behalf of the provider or the organization of which the provider entity is a part. In these instances the licensed entity shall be required to notify in writing by certified mail the Certificate of Need and Acute Care Licensure Program or the Long-Term Care Licensing and Certification Program, as applicable, at least 120 days prior to the effective date of the bed reduction identifying by number and licensure and/or health planning category the beds to be removed from the facility's license and shall specify both the total capital costs associated with the planned reduction of licensed beds and the specific plans the provider has made to relocate any and all patients occupying the beds proposed for closure. The Department shall notify the provider in writing within 20 days of receipt of written notification of the proposed bed reduction whether the proposed reduction shall require a certificate of need. The provisions of this subsection shall apply exclusively to a reduction of licensed beds which results in the permanent closure of the subject beds and their removal from the facility's license. The provisions of this subsection do not apply in the case of an applicant proposing the reduction or elimination of residential health care beds or the closure of a residential health care facility. 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. The relocation of licensed beds or services from one licensed facility to another requires a certificate of need and shall follow the full review process for relocation between different counties and the expedited review process for relocation within the same county, as follows:

i. Applications for the relocation of licensed beds or services from a licensed facility in one county to another licensed facility in a different county shall be accepted only in response to a call by the Commissioner, based on a need within a county or counties for additional beds or services.

ii. Applications for the relocation of licensed beds or services from a licensed facility in one county to another licensed facility in the same county shall, subject to the following provisions, be accepted on the first business day of each month:

(1) The facility to which the beds or services are to be relocated shall currently hold a license for the same type of beds or services. Applications for the relocation of beds or services to a facility which is not currently licensed to provide those beds or services shall not be accepted for processing;

(2) The application review process shall address all conditions of prior licensing approvals including, but not limited to, increased Medicaid costs;

(3) 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 each facility, unless one facility chooses to relocate its entire existing bed complement to the other facility and thereby remove one service entirely;

(4) Each facility shall submit an application to amend its existing license to reflect the addition or deletion of beds or services; applications shall be filed at least 30 days prior to the commencement or cessation of beds or services.

4. For projects which are exempt from the certificate of need requirement, approval from the New Jersey Department of Community Affairs prior to building construction or renovations, and 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 implementation of the bed changes shall be required, in accordance with this chapter and the Department's licensing rules.

(b) The following criteria apply to day health care facilities:

1. The establishment of, or an increase or decrease in the capacity of, an adult or pediatric day health care facility shall not require a certificate of need. However, approval from the New Jersey Department of Community Affairs prior to building construction or renovations and approval from the Department's Long-Term Care Licensing and Certification Program prior to implementation of, or changes to, adult day health care facilities/services is required, in accordance with this chapter and the Department's licensing rules.

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).

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 P.L. 1992, c.160, 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 or direct 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 health care facility or relocation to a new site within the same county as the existing health care facility shall be exempt from the certificate of need requirement, providing such replacement or relocation meets the following criteria:

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

ii. The existing facility proposed for replacement or relocation is not adding beds to its total licensed bed inventory, is not adding beds within any licensure and/or health planning category at the proposed replacement or relocated facility, and is not adding any proposed new service 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 or at a new site within the same county as the existing facility. Where the new site is in a county other than the county in which the existing facility is located, a certificate of need shall be required and shall follow the full review process, except as provided for at N.J.A.C. 8:33–5.1; and

3. Establishment of a new health care facility, satellite or replacement or relocation of an existing facility which is exempt from the certificate of need requirement requires approval from the New Jersey Department of Community Affairs, in accordance with the Department's licensing rules, prior to building construction or renovations and approval from the Department's Certificate of Need and Acute Care Licensure Program or Long-Term Care Licensing and Certification Program, as applicable, in accordance with the Department's rules, prior to operation and occupancy of the beds, service or facility.

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).

8:33–3.6 New construction/modernization/renovation

(a) Acquisition of a building and/or new construction, modernization or renovation of a health care facility which under generally accepted accounting principles, results in cumulative total project costs for all projects within a fiscal year in excess of $1,000,000, requires a certificate of need unless specifically exempted from the certificate of need requirement pursuant to P.L. 1992, c.160, sections 19 and 20 (N.J.S.A. 26:2H–7a and 7b) or as provided for at N.J.A.C. 8:33–3.4(a)lv and 6.1. 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). If the new construction, modernization or renovation is for a facility which provides a health care service which is the subject of a health planning regulation adopted by the Department, as defined at N.J.A.C. 8:33–1.3, then any person, including a physician or group of physicians, shall obtain a certificate of need prior to the initiation of the construction, modernization or renovation.

(b) Acquisition of fixed equipment and/or renovations to facilities dealing exclusively with energy conservation and management in excess of the cost thresholds for optional replacements or renovations requires a certificate of need and shall follow the expedited review process.

(c) Mandatory replacement of fixed equipment and/or mandatory renovations to facilities in excess of the monetary thresholds for equipment replacement or renovations is exempt from the certificate of need requirement. The determination of whether the replacement of fixed equipment or renovations is mandatory as defined herein shall be made by the Commissioner, based upon the professional standards, and any other standards applicable to the specific service. If the equipment replacement or renovations are not mandatory, a certificate of need shall be required and the applicant shall follow the full review process.

(d) Regardless of capital cost, a certificate of need is not required for new construction, modernization or renovation of a medical arts building or parking garage.

(e) Acquisition of a building; new construction, modernization or renovation of a health care facility; or acquisition of fixed equipment which is exempt from the certificate of need requirement requires approval from the New Jersey Department of Community Affairs prior to building construction or renovations and 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 and occupancy of the beds, service or facility, in accordance with this chapter and the Department's licensing rules.

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).

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).

8:33–3.7 Major moveable equipment

(a) Acquisition, replacement, expansion, or transfer by any person, including a physician, of major moveable equipment whose total project cost exceeds $1,000,000, as well as any major moveable equipment for the provision of a service which is the subject of a health planning regulation or which is proposed by the Commissioner to be the subject of a health planning regulation as defined at N.J.A.C. 8:33–1.3, requires a certificate of need except as follows:

1. Where the Commissioner has granted a waiver to a physician or to a health maintenance organization pursuant to section 30 of P.L. 1991, c.187, and N.J.A.C. 8:33–2.3 and 2.4;

2. Where a hospital acquires a magnetic resonance imager that is already in operation in the State by another health care provider or entity;

3. Where the purchase cost for replacement of fixed or major moveable equipment by a general acute care hospital meets the criteria set forth at N.J.A.C. 8:33–6.1(b); or

4. Where the replacement of major moveable equipment by any person, including a physician, meets the criteria set forth at N.J.A.C. 8:33–6.1(c).

(b) Acquisition of an equipment unit that is part of an equipment system, through purchase, lease, or donation, if the system's cost or value, including installation and renovation under generally accepted accounting principles, results in a cumulative total project cost or value of $1,000,000 or more or is expected to be $1,000,000 or more, within a fiscal year, requires a certificate of need and shall follow the full review process in the appropriate batch, except as provided for at N.J.A.C. 8:33–6.1(b).

(c) Any major moveable equipment acquisition which is subject to certificate of need batching requirements shall be processed in the appropriate batch and cannot be included as part of another application, such as a facility modernization/renovation/construction project.

(d) Optional replacement of existing major moveable equipment with the same equipment which exceeds the dollar threshold or which is the subject of a health planning regulation requires a certificate of need and shall follow the full review process in the appropriate batch, except as provided for at N.J.A.C. 8:33–6.1(b).

(e) Acquisition, replacement, expansion, or transfer by any person, including a physician, of major moveable equipment which requires a certificate of need shall be subject to the full review process, except as provided for at N.J.A.C. 8:33–5.1(a).

(f) Mandatory replacement of major moveable equipment as defined at N.J.A.C. 8:33–1.3, shall be exempt from the certificate of need requirement. The determination of whether the replacement equipment is mandatory as defined herein shall be made by the Commissioner, based on the professional and other standards applicable to the specific service and applicant's situation. If the equipment replacement is not mandatory, a certificate of need shall be required and shall follow the full review process in accordance with N.J.A.C. 8:33–4.1(a).

(g) Acquisition, replacement, expansion, or transfer of major moveable equipment which is exempt from the certificate of need requirement requires approval from the New Jersey Department of Community Affairs prior to building construction or renovations and 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 of the service, in accordance with this chapter and the Department's licensing rules.

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).

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/financing

(a) Any proposed increase in the total capital cost of an approved project which exceeds five percent of the initial approved total project cost shall require a change of cost review and shall follow the expedited review process outlined in N.J.A.C. 8:33–4.1(c). However, even where the additional costs fall below five percent of the initial total project cost, if the addition in and of itself would otherwise require a certificate of need, one must be obtained. Further, only one five percent increase is permitted without a change in cost certificate of need. A change of cost application must be filed with the Department prior to expenditure of funds and/or commitment to expend funds which would result in total capital costs which exceed the approved certificate of need costs. The Department shall not process any applications for changes in scope and/or cost when the changes in scope have occurred and/or costs have already been incurred and construction has been initiated or the project implemented by the time the application is submitted for processing unless the Commissioner determines that the changes arose from extraordinary unforeseeable circumstances outside the applicant's control.

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

1. In accordance with N.J.S.A. 26:2H–7a, a change of site of an unimplemented certificate of need project within the same county is exempt from certificate of need review. Entities seeking to change the site of an unimplemented certificate of need project shall submit written notification to the Certificate of Need and Acute Care Licensure Program or Long-Term Care Licensing and Certification Program, as applicable, with appropriate documentation of site control. Relocation of a proposed project which is exempt from the certificate of need requirement requires approval from the New Jersey Department of Community Affairs prior to building construction or renovations and 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 and occupancy of the beds, service or facility, in accordance with this chapter and the Department's licensing rules.

2. Relocation of the proposed project outside the approved county shall not be accepted for processing. Failure of the applicant to implement the project within the same county shall result in nullification of the certificate of need.

(c) Any change in the total approved square footage to be renovated and/or constructed does not require a certificate of need, unless it also results in an increase in total capital costs and would be subject to the criteria identified at (a) above.

(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, unless the increase is solely for the addition of assisted living or comprehensive personal care beds and as specified at N.J.A.C. 8:33–3.4 and 6.1(e), (f) and (g);

ii. Addition of approved major moveable equipment; or

iii. Addition/expansion of services approved within the application or any standard categories of health care services.

(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; 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 change in financing or change in the method of financing which shall result in an increase in capital-related operating costs of 10 percent or more shall be considered a change in the financing of the project and shall follow the expedited review process. Wherever the refinancing shall not result in an increase in capital-related operating costs of 10 percent or more, no certificate of need for a change in financing shall be required. The Department shall, however, require written notification from the approved applicant of the change that was effectuated through an approved refinancing within 30 calendar days of securing the refinancing.

(g) 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).

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. For a certificate of need approved after September 8, 1992, the certificate of need shall be valid for a period of five years from the date of approval, except that, under exceptional circumstances, the Commissioner may grant additional time or, for non-bed related health care services, less time in the initial certificate of need approval letter for completion of a project.

2. For a certificate of need approved prior to September 8, 1992, the certificate of need approval shall remain valid until the expiration date noted in the most recent extension of time.

3. 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 include documentation regarding current status of the project, 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 a final expiration date, based on the criteria contained in (a)4 below.

4. 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 timeframe identified within this subchapter, the certificate of need shall automatically be deemed to be terminated, unless the Commissioner determines that the failure of the applicant to complete the project within this timeframe was the result of extraordinary unforeseeable circumstances beyond the control of the applicant (for example, zoning litigation through the first court decision, sewer moratorium). In making this determination, the Commissioner may request the advice and comment of the State Health Planning Board and/or the local advisory board within whose boundaries the project is located.

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).

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 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 acute care 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 certificate of need pursuant to the expedited review process set forth in N.J.A.C. 8:33–5. 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 of Health and Senior Services 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 acute care teaching hospital which provides a comprehensive complement of invasive therapeutic cardiac services (that is, coronary artery by-pass graft, percutaneous transluminal coronary angioplasty, complex electrophysiology study);

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 division 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.

6. Licenses for inner city cardiac satellite demonstration project facilities may be renewed on an annual basis only upon a demonstration by the license holder to the satisfaction of the Commissioner, of full compliance with all applicable standards and criteria of this chapter; N.J.A.C. 8:43B; N.J.A.C. 8:33; N.J.S.A. 26:2H–1 et seq.; any applicable Federal law; and any additional conditions imposed upon the license holder in the original certificate of need approval.

7. These requirements for licensure shall be in addition to and not in limitation of any other applicable authorities not specifically mentioned herein and from which the facility in question has not been specifically exempted by law.

(d) The Commissioner shall accept certificate of need applications for bloodless surgery demonstration projects in accordance with the provisions of the expedited review process set forth at N.J.A.C. 8:33–5.1(a) following a call for applications.

1. The Commissioner shall approve, in writing, no more than two certificate of need applications for bloodless surgery demonstration projects in any consecutive 24–month period, beginning on August 16, 1999.

2. The Commissioner shall approve each bloodless surgical demonstration project for a period of no more than 30 months from the date of notice of the written approval, but the Commissioner, in his or her discretion, may extend the date of termination of a demonstration project upon written request made by the hospital approved for the bloodless surgical demonstration project, and the extent that the utilization, staffing, outcome, policy and procedure criteria of this rule have been achieved during the course of the demonstration period.

3. An applicant for a bloodless surgery demonstration project shall:

i. Be an acute care hospital meeting the requirements set forth at N.J.A.C. 8:33E and 8:43G; and

ii. Have an existing invasive cardiac diagnostic service that has been in compliance with the minimum annual utilization requirements at N.J.A.C. 8:33E–1.4(b)1 and the cardiac licensing requirements at N.J.A.C. 8:43G–7 for at least the three year period prior to the date of submission of the application for the bloodless surgery demonstration project.

4. An acute care hospital proposing to engage in a bloodless surgery demonstration project shall submit an application to the Department demonstrating the following:

i. That the applicant's bloodless surgery demonstration program shall serve a minimum of 100 patients per year in which each procedure, if performed conventionally, would result in a blood loss of greater than or equal to 1,000 cubic centimeters;

ii. That the applicant shall have qualified staff and staffing levels for the bloodless surgery demonstration project at all times that shall promote safety, including a bloodless surgery program coordinator who shall be a graduate of an accredited school of nursing and hold a current license to practice nursing care in New Jersey, and who shall be responsible for administration of:

(1) Patient care activities;

(2) Compilation of statistical information;

(3) Marketing activities designed to promote patient access;

(4) Physician referrals;

(5) Program staffing;

(6) Maintenance of policies and procedures; and

(7) Consultation services;

iii. That the applicant's physical plant and equipment standards for the bloodless surgery demonstration project shall result in the highest level of successful bloodless surgical outcomes;

iv. The service area for the provision of the bloodless surgery demonstration project;

v. That the applicant has developed and shall implement policies and procedures for the daily operation of the bloodless surgery demonstration project addressing, at a minimum:

(1) Hospital administration and governance;

(2) Patient services;

(3) Quality improvement;

(4) Patient health care needs;

(5) Safety and infection control;

(6) Comfort and pain management;

(7) Skin integrity;

(8) Psychosocial and spiritual health;

(9) Patient and family education;

(10) Discharge planning;

(11) Technical aspects of care; and

vi. That the applicant's bloodless surgery demonstration program will perform, at a minimum, 50 percent of its annual open heart surgery cases in accordance with the definition of "bloodless surgery" at N.J.A.C. 8:33–1.3.

5. An acute care hospital approved for a bloodless surgical demonstration project shall submit quarterly evaluation reports to the Department for the duration of the demonstration project, with a final evaluation report immediately following the completion of the demonstration project, unless the Commissioner determines and notifies the hospital in writing that the hospital shall report more or less frequently than quarterly.

i. Each evaluation report shall include documentation of the number of bloodless surgical procedures performed by type of surgery, and success rates in terms of both morbidity and mortality.

ii. Each report shall be accompanied by supporting data.

6. The standards and conditions set forth in the Commissioner's notice of approval of a bloodless surgical demonstration project shall be the applicable licensure standards for that demonstration project until the completion of the demonstration project, but shall be in addition to, not in lieu of, the general surgery licensure standards set forth at N.J.A.C. 8:43G–34, the cardiac surgery licensure standards set forth at N.J.A.C. 8:43G–7 and other licensing standards applicable for the type of surgery performed.

i. In the event that the Commissioner shall extend the period of the demonstration project by written notice, the same standards and conditions set forth in the initial notice of approval shall continue to apply during the duration of the extension of the demonstration project.

ii. All facilities seeking to initiate bloodless surgery demonstration projects described in this subchapter shall document compliance with all applicable requirements for cardiac surgery services and invasive therapeutic cardiac services as set forth at N.J.A.C. 8:33E, including facility and physician annual volume standards, personnel and staffing requirements. Compliance with the applicable requirements as set forth at N.J.A.C. 8:33E–2.1 through 2.14 shall be maintained throughout the period of the demonstration project and thereafter as required.

7. All facilities seeking to initiate bloodless surgery demonstration projects described in this subchapter shall be initially licensed in accordance with the provisions of N.J.A.C. 8:43G except as specifically set forth below.

i. Initial licenses granted to bloodless surgery demonstration projects shall be valid for a period not to exceed 30 months from the month in which the facility initiates its bloodless surgery demonstration project.

ii. Following the expiration of the initial license, licenses for bloodless surgery demonstration projects may be renewed only upon demonstration by the license holder to the satisfaction of the Commissioner of full compliance with all applicable standards and criteria of this chapter, N.J.A.C. 8:43G, N.J.S.A. 26:2H–1 et seq., any applicable Federal law, and any additional conditions imposed upon the license holder in the original certificate of need approval, and only in accordance with the following protocol:

(1) No earlier than the completion of the 24th month following the initiation of the bloodless surgery demonstration project under this program, and no later than the completion of the 26th month following the initiation of such services, all facilities seeking renewal of licenses issued pursuant to the demonstration program described in this subchapter shall submit to the Department of Health and Senior Services, documentation of their full compliance with all standards and criteria referenced in (d)7ii above, specifically including, but not limited to, the independently audited and verified criteria specified in N.J.A.C. 8:33–3.11(d)4.

(A) Failure to submit all information/documentation required for consideration of renewal in the time and manner set forth in (d)7ii(1) above, shall, absent the express written consent of the Department, constitute a basis for denial of the request for license renewal.

(B) Following the completion of the 26th month after the initiation of services under the bloodless surgery demonstration project, documentation of compliance with the requirements of (d)7ii(1) above shall only be accepted for consideration at the express written request of the Department.

(2) Upon receipt of the documentation required for renewal as set forth in (d)7ii(1) above, the Department shall review and evaluate the documentation, shall communicate with the facility to clarify and/or supplement the documentation as it in its sole discretion deems appropriate, and shall, no later than the completion of the 30th month following the month in which the facility initiated services under the bloodless surgery demonstration project, communicate a decision to the facility as to whether the license to provide services approved under this bloodless surgery demonstration project will be renewed.

(3) Facilities not receiving an express written notification of the renewal of their license authorized under the bloodless surgery demonstration project described in this subchapter in accordance with (d)7ii(2) above, shall cease all such services that were initiated as a result of the bloodless demonstration project as of the completion of the 30th month following the month in which such services were initiated and make medically appropriate referrals for all patients.

8. Notwithstanding (d)6 and 7 above, within 180 days following the promulgation of rules by the Department, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., specific to standards for bloodless surgical programs and procedures, any conditions and standards set forth in a notice of approval of a bloodless surgical demonstration project that is less stringent than, or otherwise in conflict with, the standards promulgated by the Department shall be superseded by the rules.

i. In order to maintain approval of a bloodless surgical demonstration project, each hospital with a bloodless surgical demonstration project shall submit documentation no later than 180 days following the effective date of such rules demonstrating that its bloodless surgical demonstration project is in compliance with the new or additional standards set forth by the Department.

ii. A hospital that fails to submit documentation of its compliance with the new standards, or that otherwise fails to comply with the new or additional standards shall cease its bloodless surgical demonstration project within 30 days following the date of written notice from the Commissioner of the hospital's failure to comply, except with respect to follow-up care and discharge planning for current patients participating in the bloodless surgical demonstration projects, and shall provide all necessary assistance to physicians and their patients in locating another hospital with an approved bloodless surgical program.

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).

SUBCHAPTER 4. THE REVIEW PROCESS

8:33–4.1 Request for certificate of need applications

(a) The full review process involves the review of a certificate of need application by the local advisory board(s) and the State Health Planning Board, as well as the Department. The full review process for certificate of need applications shall be activated upon notice by the Commissioner inviting certificate of need applications for specific services. The notice shall become effective upon the date of publication in the New Jersey Register. The notice shall also be distributed to the local advisory boards and to health care associations on file with 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, the date the application is deemed complete for processing, the date the local advisory board must submit its recommendation to the Commissioner and the date that the State Health Planning Board must submit its recommendation to the Commissioner. The local advisory board(s) shall forward recommendations to the State Health Planning Board and Commissioner within 45 days after the application is deemed complete for processing and 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 except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4. 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 except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4.

(b) The direct review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The direct review process for certificate of need applications shall be activated upon notice by the Commissioner inviting certificate of need applications for specific services. The notice shall become effective upon publication in the New Jersey Register. The notice shall also be distributed to the local advisory boards and to health care associations on file with 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 direct 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 will identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, the date the application is deemed complete for processing, and the date the State Health Planning Board must submit its recommendation to the Commissioner. 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 should 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, except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4. For batches with 20 or more applications, a final agency decision should 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, except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4.

(c) The expedited review process involves review of a certificate of need application by the Department. It does not include a review by the local advisory board(s) or 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 shall be rendered by the Commissioner no later than 90 days thereafter except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4.

(d) 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).

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 local advisory/board(s) in the proposed service area(s) and the Department to examine the relationship of the proposed project to the applicable plans, guidelines, and criteria. Applicants should refer to Exhibit 1 of the chapter Appendix, incorporated herein by reference, for information and assistance in determining how the proposed service area relates to the appropriate local advisory board. If the proposed service area overlaps more than one local advisory board planning region, the applicant shall contact all affected local advisory boards and the Commissioner shall invite comment from the appropriate boards.

(c) An applicant, or any principal thereof, whose certificate of need application is in any appeal or hearing status, shall not file a certificate of need application for the same health care service in the same service area which is similar to, dependent upon, or related to the application being appealed as determined by the Commissioner, while such appeal or hearing is pending.

8:33–4.3 Submission of applications

(a) Fifteen copies of the application shall be submitted to the appropriate local advisory board(s) simultaneously with 15 copies to:

Certificate of Need and Acute Care Licensure Program
New Jersey State Department of Health and Senior Services
PO Box 360, Room 604
John Fitch Plaza
Trenton, New Jersey 08625–0360
(609) 292–6552 or 292–5960

(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 (except hospital-based subacute care units); Change in the capacity of an existing facility or service (except hospital-based subacute care units); Acquisition or replacement of major moveable equipment:

Total Project Cost (TPC)	Fee Required
$1,000,000 or less	$5,000
Greater than $1,000,000	$5,000 + 0.15% of TPC
2. Hospital-based subacute care units:	$5,000
3. Change in scope of financing:	$5,000
4. Change in cost:	$5,000 + 0.15% of new TPC—initial fee
5. Extension of time	$5,000
6. 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).

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 ownership and 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 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. Where a listed principal has an ownership or 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 ownership or 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) If a management company shall be hired, the name and address of all principals in the management company shall be identified. If the certificate of need is approved, a copy of the management agreement shall be submitted to the Certificate of Need and Acute Care Licensure Program prior to licensure. Any change in management subsequent to certificate of need approval shall be reported to the Certificate of Need and Acute Care Licensure Program.

(e) 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.

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

8:33–4.5 Review for completeness

(a) The Department alone shall make the determination of the completeness status of applications. If a local advisory board chooses to comment on the completeness status of applications, it shall provide the Department with written comments 20 days after the application filing deadline. 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 and/or local advisory board. The Department shall make a decision on the completeness by the beginning of each review cycle and shall notify both the applicant and the affected local advisory board(s) of its determination. Only complete applications shall be processed. If an application has been determined to be incomplete, the Department shall notify the applicant and the appropriate local advisory board(s) in writing citing the specific deficiencies in the application. The applicant may file a new application with the appropriate information, which shall be processed in the next appropriate cycle.

(b) An application which is submitted in the incorrect batch, 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, the State Health Planning Board or the local advisory board(s). Any questions and subsequent responses shall be forwarded by the State Health Planning Board or the local advisory board(s) to the Department on a timely basis.

(d) An applicant or principal(s) shall submit a single application for beds or services subject to batching requirements and shall not submit more than one application for a given site in a given batch. Violations of this rule will result in a determination that all applications submitted by the applicant and/or principal in the given batch will be deemed **not accepted** for processing.

Case Notes

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, 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.

8:33–4.7 Deferral of applications

(a) An applicant may request in writing a deferral for up to a total of six months or, for batched applications, deferral into the next applicable batch for that service. If the applicant fails to notify the Department in writing to reactivate the application within this time frame, a new application shall be required.

(b) The local advisory board, 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 local advisory board, the State Health Planning Board, or the Department may defer the entire batch. In the case of an application or batch of applications proposed for more than one local advisory board planning region, one local advisory board may not defer without concurrence of all other local advisory boards reviewing the application or batch of applications. In the instance of projects which are the subject of a capital cap, only the Commissioner may defer any or all applications in the batch. The State Health Planning Board may recommend deferral of the entire capital batch to the Commissioner. The basis for any deferral shall be specified in writing to the applicant. The period of deferral of an individual certificate of need application or a 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 unless the applicant is required to submit new information in response to a change in the applicable requirements.

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) When a deferral is requested by the local advisory board, it shall confirm that request in writing to the Department and such requests will be reflected in the official record of the application(s).

(e) The Department shall not accept any requests for a deferral from the applicant once the State Health Planning Board or any standing committee of the State Health Planning Board authorized to make recommendations to the Board on the disposition of certificate of need applications has made its recommendation.

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 economically accomplished and maintained, shall not have an adverse economic or financial impact on the delivery of health care services in the region or Statewide, and shall contribute to the orderly development of adequate and

effective health care services. In making such determinations there shall be taken into consideration:

1. The availability of facilities or services which may serve as alternatives or substitutes;

2. The need for special equipment and services in the area;

3. The possible economies and improvement in services to be anticipated from the operation of joint central services;

4. The adequacy of financial resources and sources of present and future revenues;

5. The availability of sufficient manpower in the several professional disciplines; and

6. Other applicable requirements which are specified in any health planning rule adopted by the Department.

(b) It shall be the responsibility of the applicant to adequately and appropriately demonstrate that the proposed project meets the standards set forth in (a) above. It is not incumbent upon the reviewing agencies to demonstrate lack of need.

(c) No certificate of need shall be granted to any facility that, during the course of the application process, fails to provide or fails to contractually commit to provide services to medically undeserved populations residing or working in its service area as adjusted for indications of need. In addition, no certificate of need shall be granted to any facility that fails to comply with State and Federal laws regarding its obligation not to discriminate against low income persons, minorities, and disabled individuals.

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).
Administrative correction.
See: 30 N.J.R. 3645(a).

Case Notes

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.

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.

Denial of hospital's application to provide home health agency services was unreasonable when alleged shortcomings were also present in other approved applications. Burdette Tomlin v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 13.

8:33–4.10 Specific criteria for review

(a) Each applicant for a certificate of need shall show how the proposed project shall promote access to low income persons, racial and ethnic minorities, women, disabled persons, the elderly, and persons with HIV infections and other persons who are unable to obtain care. In determining the extent to which the proposed service promotes access and availability to the aforementioned populations, the applicant, where appropriate, shall address in writing the following:

1. The contribution of the proposed service in meeting the health related needs of members of medically undeserved groups as may be identified in the applicable local health plan and State health planning regulations as deserving of priority;

2. The extent to which medically undeserved populations currently use the applicant's service or similar services in comparison to the percentage of the population in the applicant's service area which is medically undeserved, and the extent to which medically undeserved populations are expected to use the proposed services if approved;

3. The performance of the applicant in meeting its obligation, if any, under any applicable State and Federal regulations requiring provision of uncompensated care, community services, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant);

4. How and to what extent the applicant will provide services to the medically indigent, Medicare recipients, Medicaid recipients and members of medically undeserved groups;

5. The extent to which the applicant offers a range of means by which a person will have access and availability to its service (for example, outpatient services, admission by house staff, admission by personal physician);

6. The amount of charity care, both free and below cost service, that will be provided by the applicant. In determining eligibility for this care, the applicant shall use the eligibility categories A and B of the Hill-Burton Act regulations 42 C.F.R. 124.501 et seq.;

7. Access to public or private transportation to the proposed project;

8. As applicable, effective communication between the staff of the proposed project and non-English speaking people and those with speech, hearing, or visual handicaps must be documented; and

9. Where applicable, the extent to which the project will eliminate architectural barriers to care for handicapped individuals.

(b) Each applicant for certificate of need shall demonstrate that the proposed project can be economically accomplished and maintained; that it shall address otherwise unmet needs in a particular municipality, county, and/or regional health planning area; that it shall not have an adverse economic or financial impact on the delivery of health care services; and that projected volume is reasonable. Evaluation of the applications shall include a review of:

1. Demographics of the area, particularly as related to the populations affected by the proposed project;

2. Economic status of the service area, particularly as related to special health service needs of the population; and future facility cash flow;

3. Physician and professional staffing issues;

4. Availability of similar services at other institutions in or near the service area;

5. Provider's historical and projected market shares;

6. The immediate and long term financial impact on the institution. This review shall assess:

i. Whether the method of financing identified is accurately calculated and economically feasible, and is the least cost method available;

ii. Impact of the proposed project on capital cost, operating cost, projected revenues, and charges for the year prior to the application and the two years following project completion;

iii. Impact of the proposed project on the provider's financial condition, as measured by financial statements, including balance sheets, income statements and cash-flow statements;

iv. Whether the applicant has demonstrated the ability to obtain the necessary capital funds;

v. Whether the applicant has demonstrated that the project shall result in an excess of revenue within two years after completion of the project;

vi. Whether the minimum equity requirement of at least 15 percent has been met;

(1) Equity (non-debt) is defined as a non-operating liquid asset contribution that would result in a reduction of debt. Equity may include cash, donations, net projected cash from fundraising;

(2) Land may be considered as equity if the land is included in the project cost, and the owner of the land has clear title to the land, not subject to liens or encumbrances;

(3) The appraised value of land may be considered as equity if an independent appraisal is included as part of the certificate of need application and the above criteria are met;

(4) The Commissioner may reduce the equity requirement for applicants who can demonstrate that the proposed project will primarily serve a medically undeserved population;

vii. The feasibility of refinancing both new and existing debt. When it is economically feasible, the applicant must agree to refinance; and

viii. The ability of acute care hospitals to meet the operating costs associated with the project; and

7. Each applicant for certificate of need shall demonstrate how the proposed project shall comply with applicable rules and regulations governing the construction, modernization or renovation of the project. The applicant shall address the following:

i. A cost estimate of the project stated in those dollars which would be needed to complete the project over the anticipated period of construction, assuming that construction was to begin at the time of the certificate of need submission;

ii. A detailed description of the project including square footage, construction type, current and proposed use of areas proposed for renovations, anticipated construction related circumstances, impact of asbestos abatement, accounting of all displaced department services areas, relocations and vacated areas; and

iii. The probable impact of the construction project on the costs and charges of providing health care services.

(c) For projects exceeding $15,000,000 in total project cost, institutions shall submit to the Department independently verified historical and projected financial and utilization information as identified in (b)1 through 6 above.

(d) The Commissioner may request any additional information deemed necessary to establish that the proposed project shall be economically maintained and will not adversely affect the State's health care system.

(e) Each applicant for certificate of need shall demonstrate character and competence, quality of care, and an acceptable track record of past and current compliance with State licensure requirements, applicable Federal requirements, and State certificate of need requirements, including, but not limited to, the following:

1. The performance of the applicant in meeting its obligation under any previously approved certificate of need including full compliance with the cost and scope as approved, as well as all conditions of approval;

2. Applicants shall demonstrate the capacity to provide a quality of care which meets or surpasses the requirements contained in the applicable licensing standards for the facility. Evidence of the capacity to provide high quality care shall include (e)2i below and may, if applicable, also include (e)2ii through iv below:

i. A satisfactory record of compliance with licensure standards in existing health care facilities which are owned, operated, or managed, in whole or part, by the applicant. This may include reports issued by licensing agencies from other states, as well as from the Department;

ii. Narrative descriptions or listings within the application of services, staffing patterns, policies and protocols addressing delivery of nursing, medical, pharmacy, dietary, and other services affecting residents' quality of care;

iii. Documentation of compliance with the standards of accreditation of nationally-recognized professional bodies; and

iv. Where applicable, a recommendation by the State Department of Human Services' Division of Medical Assistance and Health Services and Division of Mental Health Services regarding the quality of and access to services provided by the applicant to Medicaid patients and patients who have been discharged from State and county psychiatric hospitals;

3. The Department shall examine and evaluate the licensing track record of each applicant for the period beginning 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application, for the purpose of determining the capacity of an applicant to operate a health care facility in a safe and effective manner in accordance with State and Federal requirements. A certificate of need application may be denied where an applicant has not demonstrated such capacity, as evidenced by continuing violations or a pattern of violations of State licensure standards or Federal certification standards or by existence of a criminal conviction or a plea of guilty to a charge of fraud, patient or resident abuse or neglect, or crime of violence or moral turpitude. An application also may be denied where an applicant has violated any State licensing or Federal certification standards in connection with an inappropriate discharge or denial of admission. An applicant, for purposes of this rule, includes any person who was or is an owner or principal of a licensed health care facility, or who has managed, operated, or owned in whole or in part any health care facility, excluding individuals or entities who are limited partners with no managerial control or authority over the operation of the facility and who have an ownership interest of 10 percent or less in a corporation which is the applicant and who also do not serve as officers or directors of the applicant corporation;

4. A certificate of need application submitted by an applicant who was cited for any State licensing or Federal certification deficiency during the period identified in (e)3 above, which presented a serious risk to the life, safety, or quality of care of the facility's patients or residents, shall be denied, except in cases where the applicant has owned/operated the facility for less than 12 months and the deficiencies occurred during the tenure of the previous owner/operator. In any facility, the existence of a track record violation during the period identified in (e)3 above shall create a rebuttable presumption, which may be overcome as set forth below, that the applicant is unable to meet or surpass licensing standards of the State of New Jersey. Those applicants with track record violations which would result in denial of the application shall submit with their application any evidence tending to show that the track record violations do not presage operational difficulties and quality of care violations at the facility which is the subject of the application or in any other licensed long term care category facility in New Jersey, which is operated or managed by the applicant. If, after review of the application and the evidence submitted to rebut a negative track record, the Commissioner denies the application, the applicant may request a hearing which will be held in accordance with 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. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law. The purpose of the hearing is to provide the applicant with the opportunity to present additional evidence in conjunction with evidence already included with the initial application, for the purpose of demonstrating the applicant's operational history and capacity to deliver quality of care to patients or residents which meets or surpasses licensing standards of the State of New Jersey to the satisfaction of the Commissioner or his or her designee. The conclusion of that process with either a decision by the Commissioner or the Commissioner's acceptance or denial of an initial decision by an administrative law judge shall constitute a final agency decision. A serious risk to life, safety, or quality of care of patients or residents includes, but is not limited to, any deficiency in State licensure or Federal certification requirements (42 C.F.R. 488.400 et seq.) resulting in:

i. An action by a State or Federal agency to ban, curtail or temporarily suspend admissions to a facility or to suspend or revoke a facility's license;

ii. A decertification, termination, or exclusion from Medicaid or Medicare participation, including denial of payment for new admissions, imposed by the Department or by the Health Care Financing Administration, as a result of noncompliance with Medicaid or Medicare conditions of participation.

5. In addition to the conditions specified at (e)4 above, an application for a long-term care category service, including, but not limited to, a long-term care facility, hospital-based subacute care unit, residential health care facility, alternate family care program, pediatric or adult day health care program, assisted living residence, assisted living program or comprehensive personal care home, shall be denied upon a finding that any long-term care facility or hospital-based subacute care unit in New Jersey operated or managed by the applicant has, within the 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application, been the subject of one or more of the following:

i. A citation of any deficiency posing immediate jeopardy at a pattern or widespread scope level, or any deficiency causing actual harm at a widespread scope level, as described at 42 C.F.R. 488;

ii. A determination that the provider is a "poor performer," on the basis of a finding of substandard quality of care or immediate jeopardy, as described at 42 C.F.R. 488, on the current survey and on a survey during one of the two preceding years. For the purposes of this subchapter, "substandard quality of care" means one or more deficiencies related to participation requirements under 42 C.F.R. 483.13, Resident behavior and facility practices, 42 C.F.R. 483.15, Quality of life, or 42 C.F.R. 483.25, Quality of care, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm;

iii. A citation of a deficiency based on a finding of substandard quality of care in two different areas on the same survey. Such facilities will be afforded an opportunity to correct the deficiencies by a date specified in the Departmental notice accompanying the statement of deficiencies. If substantial compliance is achieved in all areas, the waiting period, as that term is defined in N.J.A.C. 8:33–4.10(e)10, shall terminate with the next standard survey of the facility, if that survey indicates substantial compliance. The Department shall conduct another full survey within approximately nine months of the date of the previous full survey during which the deficiencies were cited. If the deficiencies have not been corrected by the date specified in the Departmental notice accompanying the statement of deficiency, the 12–month waiting period shall commence on the date on which the deficiencies are corrected and compliance is achieved;

iv. A determination that the facility has failed to correct deficiencies which have been cited, and where this has resulted in a denial by the Department or by the Health Care Financing Administration of payment for new admissions.

6. The criteria for denial of an application specified in (e)4 and 5 above shall also result in denial of the application if the criteria are found to have been true of any number of out-of-State facilities operated or managed by the applicant, within the 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application and with respect to any service which is similar or related to the proposed service, constituting at least five percent of all facilities operated or managed by the applicant or five facilities in total, whichever is less.

7. In addition to the provisions of (e)1 through 6 above, and notwithstanding any express or implied limitations contained therein, the Commissioner may deny any application where he or she determines that the actions of the applicant at any facility operated or managed by the applicant constitute a threat to the life, safety, or quality of care of the patients or residents. In exercising his or her discretion under this rule, the Commissioner shall consider the following:

i. The scope and severity of the threat;

ii. The frequency of occurrence;

iii. The presence or absence of attempts at remedial action by the applicant;

iv. The existence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat;

v. The similarity between the service within which the threat arose and the service which is the subject of the application; and

vi. Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients or residents.

8. For the purposes of this section, similarity or relatedness of any two services is determined by the inclusion of the two services together in one of the following categories:

i. The long-term care category, which includes but is not limited to long-term care facility, hospital-based subacute care unit, residential health care facility, alternate family care program, pediatric or adult day health care program, or assisted living provided through an assisted living residence, assisted living program or comprehensive personal care home.

ii. The acute care category, which includes hospital services such as medical/surgical, pediatric, obstetric, cardiac, psychiatric, and intensive care/critical care; comprehensive rehabilitation; surgical services; magnetic resonance imaging and computerized tomography, lithotripsy; renal dialysis; and birth centers.

iii. The ambulatory care and other category, which includes primary care, home health care, family plan-

ning, drug counseling, abortion, ambulatory surgery, and outpatient rehabilitation.

iv. The substance abuse treatment category, which includes residential alcohol treatment, residential drug treatment, and outpatient drug treatment.

9. In evaluating track records pursuant to (e)3 through 8 above, the Department may consider any evidence of noncompliance with applicable licensure requirements provided by an official state licensing agency in any state other than New Jersey, or any official records from any agency of the State of New Jersey indicating the applicant's noncompliance with the agency's licensure or certification requirements in a facility the applicant owned, operated, or managed in whole or in part.

10. Any person with a history of noncompliance with statutory or regulatory requirements which, as determined by the Department, threaten the life, safety or quality of care of patients shall be ineligible to file a certificate of need application until a waiting period of at least one year has elapsed, except as specified at (e)5iii above, during which time the person must have demonstrated a record of substantial compliance with licensing or regulatory standards. The one-year period shall be measured from the time of the last licensure or certification action indicating full compliance with regulatory standards; and

11. No certificate of need application will be approved for any applicant with existing non-waiverable violations of licensure standards at the time of filing, or before final disposition of the application or for an applicant with a history of noncompliance with licensing, statutory or regulatory standards which, as determined by the Department, threaten the life, safety or quality of care of patients. An exception shall be made in the case of applications submitted for the purpose of correcting recognized major licensure deficiencies. An exception to this provision may also be granted for applications submitted for the closure or substantial reduction of underutilized beds, services, or equipment.

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).

Case Notes

Lack of sufficient record precludes finding certificate of need application's disapproval reasonable. Rolling Hills of Hunterdon Care Center, Inc. v. State Health Planning Center, 97 N.J.A.R.2d (HLT) 3.

Denial of hospital's application to provide home health agency services was unreasonable when alleged shortcomings were also present in other approved applications. Burdette Tomlin v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 13.

Denial of Certificate of Need for construction of new long-term care facility was not arbitrary and capricious. In Matter of Application of Mediplex of Voorhees for Certificate of Need. 93 N.J.A.R.2d (HLT) 37.

8:33–4.11 Notification of review cycles

The Department shall submit written notification to the local advisory board for the health planning region in which the proposed project is to be offered or developed and local advisory boards serving contiguous health planning regions, of the certificate of need applications received in a review cycle, applications deemed complete for processing and the proposed schedule for the review. The local advisory board shall be exclusively responsible for providing notification of certificate of need applications to members of the public through newspapers of general circulation and other means deemed acceptable by the local advisory board.

8:33–4.12 Functions of local advisory boards

(a) Each local advisory board shall conduct local health planning for its designated region and make recommendations at least annually to the State Health Planning Board.

(b) The local advisory board shall review certificate of need applications for proposed projects in its region and make recommendations to the Commissioner which are consistent with all appropriate health planning regulations.

(c) The local advisory board shall furnish written decisions to the Commissioner which provide the explicit basis for any recommendations made by the local advisory board on certificate of need applications. Such written decisions shall be forwarded to the Commissioner within 45 days after the application is deemed complete for processing, unless the application has been deferred pursuant to N.J.A.C. 8:33–4.7 or because of the conduct of an administrative hearing regarding one of the batched applications. These written decisions may take the form of minutes of the local advisory board.

(d) The local advisory board shall be responsible for the following activities:

1. To the extent possible, assistance to the applicant in the completion of appropriate certificate of need application forms;

2. Written notification to its service area public of the beginning of a review, which shall include notification of the proposed schedule for the review, the public comment period for persons directly affected by the review, and the manner in which public comment will be received, that is, through written comment or oral testimony;

3. Evaluation of the public need for each proposal in consideration of the criteria for review identified in N.J.A.C. 8:33–4.9 and 4.10 and in accordance with the requirements of applicable State health planning rules;

4. Review by the local advisory board staff of individual certificate of need applications for completeness and submission of applicant specific completeness questions and written notification regarding the adequacy of the applicants' responses to the Department in accordance with the timeframe set forth at N.J.A.C. 8:33–4.5;

5. Objective analysis and summary of each individual certificate of need application. A review matrix shall be completed by local advisory board staff which shall contain the appropriate statutory and regulatory criteria required to be considered on review, and shall indicate whether each applicant meets or does not meet each criterion;

6. Review by the local advisory board of the full record, including the complete certificate of need application and local advisory board staff summary, for each individual applicant. The local advisory board shall not establish any subcommittee or other standing committee for the disposition of certificate of need applications;

7. Disclosure of conflict of interest shall be made by board members prior to commencement of any review or discussion of the certificate of need applications. Board members with a conflict of interest shall remove themselves from the table and shall not participate in the discussion or vote regarding the relevant application(s);

8. The local advisory board review process shall be open to the public, with full opportunity for public participation. Written comments are encouraged, but verbal submissions shall also be permitted. Presentations made by the individual applicants shall be limited to five minutes in length. Presentations by individuals other than the applicant shall also be limited to five minutes in length. The Board meeting shall be transcribed. The Board shall conduct a roll call vote on each individual application. There shall be no need for a Board resolution. The local advisory board shall vote either to recommend approval or non-approval of each application. The Board shall state with specificity the reason(s), referencing appropriate statutory and regulatory provisions, for its recommendation, and those reason(s) shall be included with the voting summary. Approved applications which are for similar types of services shall be ranked and the rationale for the delineation between ranked approvals shall be clearly stated; and

9. The local advisory board shall notify the Commissioner and the State Health Planning Board of its recommendations by submission of the following information to the Department:

i. A summary form established by the Department which includes the local advisory board voting summary and specific reasons for decisions;

ii. A summary and review matrix;

iii. A summary of public comments for each application, which shall list specific commentors, and their affiliation(s) and shall summarize their comments (including criticisms and support); and

iv. A full transcript of the public hearing to the Department upon request.

(e) The following activities shall not be the responsibility of the local advisory boards:

1. Involvement in architectural plans review of approved projects;

2. Monitoring of the construction of approved projects;

3. Determining compliance with Department licensure requirements; or

4. Evaluating the character and competence of the applicant, based upon State licensure, survey records, or other information of State regulatory agencies.

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).

Case Notes

Health Commissioner has obligation to provide fuller explanation for rejecting appraisals than mere statement that prioritization criteria outweigh recommendations. In re Certificate of Need Application of Arnold Walter Nursing Home, 277 N.J.Super. 472, 649 A.2d 1319 (A.D.1994).

There is right to "on the merits" assessment of competing proposals. In re Certificate of Need Application of Arnold Walter Nursing Home, 277 N.J.Super. 472, 649 A.2d 1319 (A.D.1994).

8:33–4.13 Role of the State Health Planning Board

(a) The State Health Planning Board shall review applications for certificates of need and make recommendations to the Commissioner in accordance with all applicable health planning regulations.

(b) A member of the State Health Planning Board shall not vote on any matter before the board concerning an individual or entity with which the member has, or within the last 12 months has had, any substantial ownership, employment, medical staff, fiduciary, contractual, creditor or consultative relationship. A member who has or has had such a relationship with an individual or entity involved in any matter before the board shall make a written disclosure of the relationship before any action is taken by the board with respect to the matter and shall make the relationship public in any meeting in which action on the matter is to be taken. Board members with a conflict of interest shall remove themselves from the table and shall not participate in the discussion of the relevant application(s).

(c) The State Health Planning Board shall furnish written decisions to the Commissioner which provide the explicit basis for any recommendations made by the Board on certificate of need applications. Such written decisions shall be forwarded to the Commissioner within 90 days after the application is deemed complete for processing unless the application has been deferred pursuant to N.J.A.C. 8:33–4.7 or because of the conduct of an administrative hearing regarding one of the batched applications. These written decisions may take the form of minutes of the State Health Planning Board.

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).

Case Notes

Appeal from denial of certificate of need. St. Joseph's Hospital and Medical Center v. Finley, 153 N.J.Super. 214, 379 A.2d 467 (App.Div. 1977), certification denied 75 N.J. 595, 384 A.2d 825 (1978). St. Vincent's Hospital v. Finley, 154 N.J.Super. 24, 380 A.2d 1152 (App. Div.1977). Irvington General Hospital v. Dept. of Health, 149 N.J.Super. 461, 374 A.2d 49 (App.Div.1977). National Nephrology Foundation v. Dougherty, 138 N.J.Super. 470, 351 A.2d 392 (App.Div.1976).

No private right of action. Delaware Valley Transplant Program v. Coye, D.N.J.1989, 722 F.Supp. 1188.

Res judicata did not preclude federal district court from considering claim of Delaware organ procurement agency that decision to authorize as sole statewide procurer was impermissible. Delaware Valley Transplant Program v. Coye, D.N.J.1989, 722 F.Supp. 1188.

Either transcript or minutes of state health board's meeting could serve as required "written decision" regarding recommendations on certificate of need (CON) applications, so long as document in question contained particularized explanation of reasons for grant or denial of CON. Application of Holy Name Hosp., 301 N.J.Super 282, 693 A.2d 1259 (1997).

State Health Planning Board required to explain its recommendations regarding certificate of need applications. In Re Hospital Home Care, Inc., 96 N.J.A.R.2d (HLT) 50.

Denial of certificate of need on basis of low priority ranking of local advisory board was not unreasonable. Alternative Health Care of Gloucester v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 33.

Denial of Certificate of Need for construction of new long-term care facility was not arbitrary and capricious. In Matter of Application of Mediplex of Voorhees for Certificate of Need. 93 N.J.A.R.2d (HLT) 37.

8:33–4.14 Procedures for review by local advisory boards and the State Health Planning Board

(a) If at least 25 percent of the quorum of voting members at a meeting of a local advisory board votes affirmatively to approve a certificate of need application, regardless of whether the local advisory board's recommendation is to approve or deny the application, the application shall be forwarded to the State Health Planning Board for its review of the application. If the application does not receive the required minimum number of affirmative votes, the application shall not be submitted to the State Health Planning Board or the Commissioner for their reviews, respectively.

(b) If at least 25 percent of the quorum of voting members at a meeting of the State Health Planning Board votes affirmatively to approve a certificate of need application, regardless of whether the State Health Planning Board's recommendation is to approve or deny the application, the application shall be forwarded to the Commissioner for his or her review of the application. If the application does not receive the required minimum number of affirmative votes, the application shall not be submitted to the Commissioner for his or her review.

(c) If an application does not receive the required minimum number of affirmative votes by either a local advisory board or the State Health Planning Board, respectively, the applicant may request a fair hearing to permit the application to move to the next level for review. The request for a fair hearing shall be made to the Commissioner within 30 days of the vote by the local advisory board or State Health Planning Board, as applicable. The fair hearing shall be held within 60 days of the request. If the Administrative Law Judge determines that the application should be reviewed by the next level for review, the applicant shall be so notified and the State Health Planning Board or the Commissioner, as applicable, shall review the application.

1. If a request for fair hearing is received within 30 days, it shall be forwarded to the Office of Administrative Law where it shall be processed expeditiously.

2. The Administrative Law Judge will review the reasonableness of the local advisory board's or State Health Planning Board's reasons for denial, as stated in its written decision, based on the documenting evidence that was presented to the local advisory board or State Health Planning Board. No other documentation may be introduced during the course of the hearing.

3. The decision of the Administrative Law Judge on whether the certificate of need application should proceed to the next step in the review process shall be the final decision.

4. All certificate of need applications competing for the same service in the same area shall be deferred by the Department until a final decision is rendered.

5. The process shall be reactivated at the next appropriate step (to the State Health Planning Board or to the Commissioner) upon notice of the final decision of the Administrative Law Judge.

Case Notes

No private right of action. Delaware Valley Transplant Program v. Coye, D.N.J.1989, 722 F.Supp. 1188.

Res judicata did not preclude federal district court from considering Delaware organ procurement agency's claim that State's decision to authorize sole statewide procurer was impermissible. Delaware Valley Transplant Program v. Coye, D.N.J.1989, 722 F.Supp. 1188.

Health Commissioner has obligation to provide fuller explanation for rejecting appraisals than mere statement that prioritization criteria outweigh recommendations. In re Certificate of Need Application of Arnold Walter Nursing Home, 277 N.J.Super. 472, 649 A.2d 1319 (A.D.1994).

There is right to "on the merits" assessment of competing proposals. In re Certificate of Need Application of Arnold Walter Nursing Home, 277 N.J.Super. 472, 649 A.2d 1319 (A.D.1994).

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).

Appeal from denial of certificate of need; in absence of any showing of fraud or bad faith on part of successful applicant for certificate of public need for cardiac surgical program, rejected applicants were limited in their challenge of Commissioner's decision. Application of Overlook Hospital, 215 N.J.Super. 401, 521 A.2d 1350 (App.Div.1987).

Local advisory board's less than minimum number of affirmative votes defeats application for certificate of need. In the Matter of the Application of Holy Name Hospital, 96 N.J.A.R.2d (HLT) 53.

State Health Planning Board's denial of Certificate of need applications unlawful and unreasonable when Board fails to give written justification. Olsten Certified Health Care Corp. v. State Health Planning Board, 96 N.J.A.R.2d (HLT) 31.

Local advisory board not arbitrary or unreasonable in disapproving batch of applications for certificates of need by single vote. JFK Hartwyck at Oak Tree, Inc., v. Mid-State Health Advisory Corp., 96 N.J.A.R.2d (HLT) 18.

Hospital's certificate of need application not afforded fair and reasonable review. Bacharach Rehabilitation Hospital v. State Health Planning Board, 96 N.J.A.R.2d (HLT) 15.

State health board's denial of certificate of need application not reasonable when board fails to issue written decision. Wills/MMDC-Cape May County Court House Partnership v. State Health Planning Board, 96 N.J.A.R.2d (HLT) 8.

Denial of certificate of need on basis of low priority ranking of local advisory board was not unreasonable. Alternative Health Care of Gloucester v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 33.

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.

Denial of application for certificate of need was unreasonable without an accompanying written decision evaluating specific criteria. Tri–Med v. State Health Planning Board, 95 N.J.A.R.2d (HLT) 22.

Denial of medical center's application for certificate of need could not be reviewed for reasonableness in absence of a specific articulation in record of reasons for denial. In Re Hunterdon Application, 95 N.J.A.R.2d (HLT) 11.

Appeal from denial of certificate of need; reimbursement for construction costs which exceeded the approved project cost denied as untimely; denial of reimbursement for petitioner's interest amortization rate. Hillcrest Manor v. Dep't of Human Services, 9 N.J.A.R. 45 (1983).

8:33–4.15 Procedures for Commissioner review

(a) The Commissioner may approve or deny an application for a certificate of need if the approval or denial is consistent with all applicable health planning rules. The Commissioner shall issue a written decision on his or her determination of a certificate of need application which shall specify the reasons for approval or disapproval. The decision shall be sent to the applicant, to the appropriate local advisory board and to the State Health Planning Board, and shall be available to others upon request.

(b) Pursuant to N.J.S.A. 26:2H–9, if the Commissioner denies a certificate of need application, the applicant shall be granted an opportunity for fair hearing to contest the Commissioner's action. Further, no decision shall be made by the Commissioner contrary to the recommendation of the State Health Planning Board on the disposition of a certificate of need application unless the State Health Planning Board and the applicant shall be granted an opportunity for a hearing.

(c) A request for a fair hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's decision. The fair hearing shall be conducted according to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, and the record shall be limited to the documentary evidence presented to the reviewing agencies below. The Health Care Administration Board, within 30 days of receiving all appropriate hearing records, or, in the absence of a request for a hearing within 30 days of receiving the denial recommendations of the Commissioner, shall make its determination.

(d) After the commencement of a fair hearing pursuant to (c) above, and before a decision is made, there shall be no ex parte contacts between any person acting on behalf of the applicant or holder of a certificate of need, or any person opposed to the issuance of a certificate of need, and any person in the Department who exercises any responsibility for reviewing the application. Ex parte communication is defined as an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given. It shall not include requests for status reports on any matter or proceeding. Any communications made after commencement of the fair hearing that are placed in the record of the proceedings are made available to all parties are not ex parte and are not prohibited.

(e) The determination of the Health Care Administration Board is the final decision of the Department where the Commissioner has recommended denial of a project application or where his or her decision to approve is contrary to the recommendation of the State Health Planning Board or the local advisory board and a fair hearing is requested and held.

(f) The Department shall notify, upon their request, providers of health services and other persons subject to certificate of need requirements of the status of the review of certificate of need applications, findings made in the course of such review, and other information respecting such review after the certificate of need is deemed complete for processing.

(g) If the Department determines that the holder of an unimplemented certificate is not making a good faith effort to implement the project, the Commissioner may null and void the certificate. Prior to such a determination, the Department shall notify the holder of the certificate of its intent to initiate the nullification process. The holder of the Certificate shall have 30 days from the date of such notice to submit written documentation of the substantial progress which has been made, and which will continue, in implementing the Certificate. If, after the review of the documentation submitted, a notice of nullification is nevertheless issued, the holder may request a hearing pursuant to (c) above.

Case Notes

Commissioner of Health's conclusory determinations were not sufficient to show that certificate of need was properly granted. In re Valley Hosp., 240 N.J.Super. 301, 573 A.2d 203 (A.D.1990), certification denied 126 N.J. 318, 598 A.2d 879.

State Health Planning Board's decision not to forward health care provider's certificate of need application to Commissioner of Health not reasonable. In the Matter of VNA of Central Jersey, 96 N.J.A.R.2d (HLT) 63.

8:33–4.16 Conditions on approval/monitoring

(a) Conditions may be placed on certificate of need approval by the Commissioner if they relate to material presented in the application itself, are prescribed in State rules, relate to the criteria specified in N.J.A.C. 8:33–4.9 and 4.10 or promote the intent of the Health Care Facilities

Planning Act, N.J.S.A. 26:2H–1 et seq., as amended. The State Health Planning Board and local advisory board shall not recommend the inclusion of conditions in a certificate of need approval which are not consistent with the provisions of this subchapter.

(b) Any conditions placed on a certificate of need approval shall become part of the licensure requirements of the approved facility. Failure to comply with conditions of approval may result in licensure action by the Department and may constitute an adequate basis for denying certificate of need applications by an applicant who is out of compliance with conditions on previous approvals. The applicant must contest any condition, if at all, within 30 days of receipt of notice. The applicant shall vacate his right to oppose said condition(s) if he fails to submit written notice that he contests any condition to the Department within this time. If the applicant contests a condition, the Commissioner shall suspend his or her approval of the certificate of need in order to consider the objection. Furthermore, the Commissioner has the right to nullify the approval of the certificate of need. The Commissioner may, at his or her discretion, consult with the State Health Planning Board to obtain its recommendation on the contested condition(s).

(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 result in the nullification of the unimplemented certificate of need, fines and penalties imposed through licensure action and/or taken into consideration in the review of subsequent certificate of need applications.

(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).

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33–5.1 Statement of purpose

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

1. Establishment of a residential health care facility;

2. Establishment of a Statewide restricted admissions facility or change in bed capacity of a Statewide restricted admissions facility;

3. Change in cost, scope or financing to an unimplemented certificate of need;

4. Establishment of or changes in the bed capacity of comprehensive personal care homes;

5. Establishment of an obstetric service by a general acute care hospital or increases in the obstetric bed capacity of a general acute care hospital in excess of the exception criteria at N.J.A.C. 8:33–3.4 and 6.1;

6. Establishment of a pediatric service by a general acute care hospital or increases in the pediatric bed capacity of a general acute care hospital in excess of the exception criteria at N.J.A.C. 8:33–3.4 and 6.1. This provision does not apply to pediatric intensive or critical care beds and/or services;

7. Establishment of a birth center;

8. Establishment of or an increase in the capacity of medical/surgical beds dedicated as a medical detoxification program by a general acute care hospital;

9. Establishment of or an increase in the bed capacity of a residential alcohol treatment facility;

10. Establishment of or an increase in the bed capacity of a residential drug treatment facility;

11. Establishment of a comprehensive outpatient rehabilitation facility;

12. Establishment of or additions to an ambulatory surgery facility or operating room capacity dedicated to ambulatory surgical or same day surgical cases, except as provided for at N.J.A.C. 8:33–6.1(d);

13. Establishment of an acute hemodialysis service by a licensed general acute care hospital;

14. Acquisition by a general acute care hospital of megavoltage radiation oncology equipment that is already in operation in the State of New Jersey by another health care provider or entity that is currently providing radiation oncology services to patients in New Jersey;

15. Acquisition of magnetic resonance imaging/nuclear magnetic resonance equipment and/or establishment or expansion of a magnetic resonance imaging/nuclear magnetic resonance service;

16. Acquisition of hyperbaric chamber equipment and/or establishment or expansion of a hyperbaric chamber service;

17. Establishment of an ambulatory care facility or provision of an ambulatory care service, except that an ambulatory care facility or service that is the subject of a health planning regulation shall follow the full review process in accordance with N.J.A.C. 8:33–4.1(a).

18. Replacement of major moveable equipment which exceeds the dollar thresholds at N.J.A.C. 8:33–6.1(b) and (c);

19. Establishment of or changes in the capacity of assisted living residences;

20. Establishment of or changes in the capacity of alternative family care programs;

21. Establishment of or changes in the capacity of assisted living programs;

22. Establishment of or increases in the capacity of hospital subacute care units, which shall be comprised of not more than seven percent of the hospital's licensed medical/surgical bed capacity or 12 beds, whichever is greater; and

23. Extension of time to an unimplemented certificate of need.

24. 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.

25. Establishment of an inner city cardiac satellite demonstration project as defined at N.J.A.C. 8:33–1.3 and consistent with the criteria set forth at N.J.A.C. 8:33–3.11.

26. Establishment of a hospital-based subacute care unit.

27. Establishment of bloodless surgery demonstration projects in accordance with N.J.A.C. 8:33–3.11(d).

(b) The expedited review process may also be used in lieu of the full or direct review process, as noted in these rules, 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.

8:33–5.2 Process

(a) The expedited review process shall include 12 review cycles. 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 thereafter. Applications received after the first business day of the month shall be processed in the next month's cycle.

(b) Applications shall be reviewed to determine whether they are acceptable for processing. All applications shall be signed and dated by the applicant; accompanied by the correct application fee, out-of-State track record reports with 10 xerox copies; and completely and accurately filled out. Applications not meeting these requirements shall not be accepted for processing. Applications that are not accepted for processing shall be returned to the applicant, along with the application fee.

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

(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) Interested parties, including the State Health Planning Board, the Health Care Administration Board, local advisory boards, shall be notified by the Department of the expedited review applications deemed acceptable for processing.

(f) 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 10 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 604
Trenton, New Jersey 08625–0360
(609) 292–6552 or 292–5960

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

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, operating costs and revenues, square footage, 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;

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

iii. Financial information that includes the impact of the proposed project on the provider's financial condition, as measured by financial statements, including balance sheets, income statements and cash flow statements.

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

5. Applicants for a change in cost shall also comply with N.J.A.C. 8:33–5.4.

Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

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 a change in cost or financing, a description of new capital costs and financing costs by category and new financing alignment; or

2. For an ambulatory surgery facility or additions to operating room capacity dedicated to same day surgical cases:

i. The proposed number of ambulatory/same day surgery operating rooms;

ii. Pro forma showing all capital and operating costs and revenues to one year beyond break even;

iii. The expected number of recovery beds and/or recliners;

iv. Documentation as to whether the physician(s) associated with the ambulatory surgical facility accepts Medicare and Medicaid assignment or has a contractual relationship with the managed care entity with whom the Medicaid Program has a contract;

v. Documentation as to the proportion of Medicaid-eligible and medically indigent persons residing in the proposed service area and a written statement from the applicant that the applicant will, in delivering the proposed service, provide care on a free or partial pay basis to Medicaid-eligible and medically indigent persons at least in proportion to their representation in the approved service area;

vi. Documentation that the applicant has initiated contacts with community organizations which serve low income populations; and

vii. Documentation that the ambulatory surgery facility shall comply with the State Uniform Construction Code, at N.J.A.C. 5:23–3, and the Department's licensing rules.

3. For a hospital-based subacute care unit:

i. Acknowledgment that the unit shall be comprised of not more than 7 percent of the hospital's licensed medical/surgical bed capacity or 12 beds, whichever is greater;

ii. Acknowledgment that the hospital's licensed medical/surgical bed capacity shall be reduced by the number of beds used to establish a hospital-based subacute care unit;

iii. Acknowledgment that long-term care beds in a hospital-based subacute care unit shall not be transferred to, or combined with, a hospital-based subacute care unit in another hospital or division. Bed limitations for a hospital shall include both conversions of existing acute care beds and any purchases or other acquisitions or rentals of beds to be used by a hospital for the provision of subacute care; and

iv. Acknowledgment that subacute care shall not be covered by the Medicaid program established pursuant to P.L. 1968, c.413 (N.J.S.A. 30:4D–1 et seq.).

4. 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)24:

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.

(b) Applicants who receive certificate of need approval for ambulatory surgical services shall provide the following information on an annual basis to the Department's Certificate of Need and Acute Care Licensure Program. The report covering the previous calendar year shall be filed no later than April 1 of each year.

1. Characteristics of patients, including: age, sex, race, ethnicity, residence (county/municipality), payer, diagnosis and total number of surgical cases.

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.

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, 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. Increases or decreases in the bed capacity of residential health care facilities;

6. Mandatory renovations to existing facilities;

7. Mandatory replacement of fixed or moveable equipment;

8. Transfer of ownership interest, except in the case of a general acute care hospital, or a long-term care facility in which the new owner does not satisfy the Department's review of the new owner's prior operating experience in accordance with the criteria identified at N.J.A.C. 8:33–4.10 and N.J.A.C. 8:33H, as well as any requirements established by the Federal government pursuant to Titles XVIII and XIX of the Social Security Act (42 U.S.C. § 483.1 through 483.158).

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

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

11. 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;

12. Acquisition by a general acute care hospital of a magnetic resonance imager that is already in operation in the State by another health care provider or entity;

13. Adult day health care facilities;

14. Pediatric day health care facilities; and

15. Chronic renal dialysis facilities.

(b) In accordance with the provisions of the Health Care Reform Act, P.L. 1992, c.160, section 20 (N.J.S.A. 26:2H–7b), modernization, renovation, and/or replacement of fixed or major moveable equipment by a general acute care hospital shall be exempt from the certificate of need requirement providing it meets the following criteria:

1. Where the total project or purchase cost does not exceed five percent of that hospital's operating revenues for the year in which the project or purchase is undertaken, a certificate of need is not required.

i. For purposes of this subsection, the total project is defined as the compilation, during a single calendar year, of architectural, engineering and/or construction services for renovations provided by individuals or firms which are not employees of the hospital and for which financing is required to fund the project.

ii. For purposes of this subsection, if the hospital incurs capital expenditures without use of the external services as described above, then each planned renovation of any discrete area or unit of the hospital shall be considered a separate project.

iii. For purposes of this subsection, purchase cost is defined as the cost of acquisition of a single unit of fixed or major moveable equipment, including installation and renovation.

iv. For purposes of this subsection, operating revenues will be defined as total operating revenues from the hospital's most recent year audited financial statements, which shall be inflated using a global economic factor which measures the change in the prices of goods and services used by New Jersey hospitals.

2. This exemption shall not apply to the initiation or expansion of any health care service as provided in section 2 of P.L. 1971, c.136 (N.J.S.A. 26:2H–2), as amended, which includes a health care service that is identified in the Appendix, Exhibit 2, the expansion of a hospital's physical plant; or the construction of a new health care facility.

(c) Replacement of major moveable equipment by any person, including a physician, shall be exempt from the certificate of need requirement providing it meets the following criteria:

1. The total project cost including installation and renovation is $1,000,000 or less; and

2. The replacement maintains existing capability and does not include upgrading to a newer technology that expands the range of service.

(d) A physician or physician professional association seeking to establish and maintain a single operating room surgical practice solely limited to his or her or their private practice shall be exempt from the certificate of need requirement.

(e) A long-term care facility proposing to increase its total number of licensed long-term care beds by no more than 10 beds or 10 percent of its licensed long-term care capacity, whichever is less, within a period of five years shall be exempt from the certificate of need requirement.

(f) An acute care hospital proposing to increase its total number of licensed medical/surgical beds by no more than 20 percent of its licensed medical/surgical bed capacity within a period of five years shall be exempt from the certificate of need requirement.

(g) An acute care hospital proposing to increase its total number of licensed ob/gyn, pediatric (excluding intensive or critical care), or adult ICU/CCU beds by no more than 10 beds or 20 percent of its licensed capacity in the licensure bed category, whichever is less, within a period of five years shall be exempt from the certificate of need requirement.

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

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

8:33–6.2 Process

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

(b) For mandatory replacement of fixed or major moveable equipment or mandatory renovations to existing facilities, an explanation of the mandatory nature, including a written opinion regarding hazards and safety effects upon patient care by experienced professionals, or from Federal, State, county or municipal governmental agencies, shall be submitted to the Commissioner for a determination prior to proceeding with the replacement or renovations.

(c) For community-based primary care centers, including family planning centers, not specifically identified herein, a description of the proposal, including services to be offered, staffing, population to be served and anticipated revenue sources, shall be submitted to the Commissioner for a determination regarding certificate of need requirements prior to proceeding with initiation of services at the proposed facility, in accordance with the provisions of this chapter.

(d) 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.

(e) Written notification and architectural plans shall be submitted to the New Jersey Department of Community Affairs for approval prior to initiating building construction or renovations, in accordance with this chapter and the Department's licensing rules.

(f) Written notification 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, for approval prior to operation and occupancy of the beds, service or facility in accordance with this chapter and the Department's licensing rules.

(g) 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 rule.

SUBCHAPTER 7. DIRECT REVIEW PROCESS

8:33–7.1 Statement of purpose

(a) The direct review process shall be used for health care services for which need is derived from an evaluation of the entire State, including, but not limited to, the following specific health care services:

1. Special child health clinics providing tertiary services;
2. Burn care services;
3. Transplantation services;
4. Emergency medical service helicopters;
5. Positron emission tomography scanning;
6. Organ bank; and
7. New health/medical technologies that are identified by the Department as having a Statewide impact.

8:33–7.2 Process

(a) The direct review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The direct review process for certificate of need applications shall be activated upon notice by the Commissioner inviting certificate of need applications for specific services. The notice shall become effective upon publication in the New Jersey Register. The notice shall also be distributed to the local advisory boards and to health care associations on file with 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 direct 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. If the New Jersey Register publication schedule permits, 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). This notice shall identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, the date the application is deemed complete for processing, and the date the State Health Planning Board must submit its recommendation to the Commissioner. 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, except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4. 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 except where a hearing is requested as set forth in N.J.A.C. 8:33–4.10(e)4.

(b) The State Health Planning Board review process for direct review shall be open to the public, with full opportunity for public participation. Written comments are encouraged, and verbal presentations shall be permitted by individual applicants and other interested parties.

APPENDIX

EXHIBIT 1
LOCAL ADVISORY BOARDS IN NEW JERSEY

Region	Name of Agency	Counties served
I	New Health Initiatives, Inc.	Hunterdon Mercer Middlesex Morris Passaic Somerset Sussex Warren
II	Seton Hall University/Northeast Regional Health Planning, Inc.	Bergen Essex Hudson Union
III	Jersey Coast Health Planning Council, Inc.	Atlantic Burlington Camden Cape May Cumberland Gloucester Monmouth Ocean Salem

EXHIBIT 2
Health Care Services

A. Bed-related
1. Medical/Surgical
2. Obstetrics, gynecology
3. Pediatric
4. Adult and pediatric intensive or critical care
5. Cardiac care
6. Comprehensive rehabilitation
7. Long-term care and specialized long-term care
8. Residential health care
9. Adult acute psychiatric (open and closed)
10. Adult intermediate and special psychiatric
11. Child and adolescent acute psychiatric
12. Child and adolescent intermediate psychiatric
13. Alcohol detoxification
14. Alcohol residential treatment
15. Drug free residential
16. Hospital-based subacute care

B. Non-bed-related
1. Home health agency
2. Comprehensive outpatient rehabilitation facility
3. Surgical facility
4. Special child health clinics providing tertiary services
5. Ambulatory care facility

C. Special Services
1. Acute renal dialysis
2. Invasive cardiac diagnostic services
3. Burn center, unit or program
4. Cardiac surgical services
5. Organ transplant/organ procurement
6. Megavoltage radiation oncology
7. Organ bank
8. Perinatal services including neonatal intensive or intermediate services and maternal and child health consortia
9. Mobile intensive care or advanced life support services
10. Position emission tomography services
11. Magnetic resonance imaging and nuclear magnetic resonance services
12. Extracorporeal shock wave lithotripsy services
13. Birth centers
14. Comprehensive personal care home
15. Assisted living residence
16. Bone marrow transplant/harvesting including stem cell
17. Trauma services
18. Children's hospitals
19. Hyperbaric chambers
20. Emergency medical service helicopters
21. Central service agency
22. Community Perinatal Center-Basic
23. Community Perinatal Center-Intermediate
24. Community Perinatal Center-Intensive
25. Regional Perinatal Center
26. Alternate family care program
27. Assisted living program
28. Any service for which regionalization criteria or health planning regulations have been developed.
29. Other new health/medical care technologies including any medical equipment which has received FDA premarketing approvals.

EXHIBIT 3
EXAMPLES OF MAJOR MOVEABLE EQUIPMENT

Cardiac catheterization laboratory equipment
Extracorporeal shock wave lithotripter (kidney and/or biliary)
Linear accelerator (including Cobalt 60 unit)
Nuclear magnetic resonance and magnetic resonance imaging equipment
Positron emission tomography (PET)

EXHIBIT 4
Certificate of Need Review

	Type of Review
BED-RELATED HEALTH CARE FACILITY/SERVICES	
Establishment of or Additions to Existing:	
Medical detoxification program (hospital-based)	Expedited
Alcohol residential treatment facility	Expedited
Assisted living program	Expedited
Assisted living residence	Expedited

	Type of Review
Children's hospital	Full
Comprehensive rehabilitation hospital (inpatient)	Full
Comprehensive personal care home	Expedited
Drug free residential treatment facility	Expedited
General acute care hospital	Full
Hospital-based subacute care unit	Expedited
Long-term care facility (new and additions greater than 10 beds or 10 percent, whichever is less)	Full
Obstetric service	Expedited
Pediatric service (excluding intensive/critical care)	Expedited
Pediatric service (intensive/critical care)	Full
Psychiatric hospital (acute)	Full
Psychiatric hospital (intermediate and special)	Full
Residential health care facility (new)	Expedited
Special hospital	Full
Statewide restricted admissions facility	Expedited
Decrease in beds	
Bed decrease with cost greater than 5 percent (acute care hospital)	Full
Bed decrease with cost greater than $1 million (all other health care facilities)	Full
NON-BED RELATED HEALTH CARE SERVICES/FACILITIES	
Alternate family care program	Expedited
Ambulatory care (not community based primary care)	Expedited
Ambulatory surgery facility	Expedited
Birth Center (new)	Expedited
Bone marrow transplant/harvesting including stem cell	Direct
Burn center, unit or program	Direct
Cardiac diagnostic services/invasive (catheterization)	Full†
Cardiac surgical service	Full
Cardiac transplant service	Full
Central service agency	Full
Comprehensive outpatient rehabilitation facility (new)	Expedited
Emergency medical service helicopter	Direct
Hemodialysis (acute)	Expedited
Home health agency	Full
Hyperbaric chamber	Expedited
ICU/CCU beds (except as provided for at N.J.A.C. 8:33-3.4(a)1iv)	Full
Kidney transplant service	Full
Lung transplant service	Full
Magnetic resonance imaging/nuclear magnetic resonance (new)	Expedited††
Megavoltage radiation oncology (new)	Full
Megavoltage radiation oncology (transfer existing private)	Expedited
Mobile intensive care or advanced life support service	Full†††
Operating room (addition/replacement) hospital based	Full
Operating room (inpatient/mixed) renovation (hospital based) renovations greater than 5 percent new construction greater than $1 million	Full
Organ bank	Direct
Organ transplantation procurement	Direct
Perinatal service, including neonatal intensive or intermediate services and maternal and child health consortia	Full
Positron emission tomography scanning	Direct
Special child health clinics providing tertiary services	Direct
Trauma service	Full
Any other new health/medical care technologies that the Department identifies as having a Statewide impact	Direct
Any other new health/medical care technologies that the Department identifies as having a regional impact	Full
ACQUISITION OF MAJOR MOVEABLE EQUIPMENT	
Establishment of new service or addition to existing service Cardiac catheterization laboratory equipment	Full†
Extracorporeal shock wave lithotripter (kidney and/or biliary)	Full
Hyperbaric chamber	Expedited
Linear accelerator (including Cobalt 60 unit)	Full
Magnetic resonance imaging/nuclear magnetic resonance	Expedited
Positron emission tomography	Direct
Replacement of major moveable equipment with same type of equipment	
Greater than 5 percent (acute care hospitals)	Expedited
Greater than $1 million (all other health care providers)	Expedited
REPLACEMENT OF EXISTING NON-BED SERVICE	
Greater than 5 percent (acute care hospitals)	Expedited
REPLACEMENT OF BEDS	
Greater than 5 percent (acute care hospitals)	Full
Greater than $1 million (all other providers)	Full
RELOCATION OR REPLACEMENT OF AN EXISTING LICENSED FACILITY	
Acute care hospital/within or outside county	Full
All other/within same county	Exempt
All other/outside county	Full
RELOCATION OF LICENSED BEDS	
Outside county of original location	Full
Within same county	Expedited
TERMINATION/DISCONTINUANCE OF LICENSED BEDS, SERVICES OR FACILITIES	
Acute care hospitals	Full
Acute care hospitals—decrease in beds costing less than 5 percent of total annual operating revenues	Expedited
Component service with problems of access	Expedited
TRANSFER OF OWNERSHIP—OPERATING FACILITY	
General acute hospitals	Full
LTC with track record deficiency history	Expedited
TRANSFER OF OWNERSHIP—UNIMPLEMENTED CERTIFICATE OF NEED	
Less than ten percent transfer of stock	Expedited
Limited partnership interests	Expedited
Membership of nonprofit corporations	Expedited
Death of applicant	Expedited
Change in entity without change in principals	Expedited
CONSTRUCTION, RENOVATION, MODERNIZATION	
Greater than five percent (acute care hospitals)	Full
Greater than $1 million (all other health care facilities)	Full
CHANGE IN COST TO UNIMPLEMENTED CN	

	Type of Review
All	Expedited
CHANGE IN FINANCING TO UNIMPLEMENTED CN	
Capital-related operating costs greater than 10 percent	Expedited
CHANGE IN SCOPE TO UNIMPLEMENTED CN (Beds, MME, Services)	
Increase in beds/MME/Services	Not Accepted
CHANGE OF SITE/UNIMPLEMENTED CN	
Within same county	Exempt
Outside county	Not Accepted

CN = Certificate of Need
LTC = long-term care
MME = major moveable equipment
NAP = not accepted for processing
RHC = residential health care
s.f. = square footage
5% = 5% of the acute care hospital's operating revenues for the year in which the project or purchase is undertaken

† Low risk pilot catheterization program, as defined at N.J.A.C. 8:33E, will be subject to the expedited review process.

†† No CN is required for the acquisition by a general acute care hospital of magnetic resonance imaging equipment that is already in operation in the State by another health care provider or entity.

††† Additions to the number of vehicles or hours of operation by an ALS/MICU service licensed by the Department requires notification to the Department's Office of Emergency Medical Services only. Reductions to the number of vehicles or hours of operation by an ALS/MICU service licensed by the Department requires notification to, and approval from, the Department's Office of Emergency Medical Services.