

CHAPTER 33
CERTIFICATE OF NEED: APPLICATION
AND REVIEW PROCESS

Authority

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

Source and Effective Date

R.1992 d.342, effective September 8, 1992.
 See: 24 N.J.R. 2222(a), 24 N.J.R. 3104(a).

Executive Order No. 66(1978) Expiration Date

Chapter 33, Certificate of Need: Application and Review Process, expires September 8, 1997.

Chapter Historical Note

All provisions of this chapter became effective on May 11, 1972, as R.1972 d.93. See: 4 N.J.R. 25(a), 4 N.J.R. 124(a). Amendments were filed October 21, 1975, as R.1975 d.315 to become effective on December 1, 1975. See: 7 N.J.R. 362(a), 7 N.J.R. 503(a). Amendments were filed and became effective July 20, 1979 as R.1979 d.283. See: 11 N.J.R. 174(a), 11 N.J.R. 439(a). Amendments were filed and became effective January 17, 1980 as R.1980 d. 36. See: 11 N.J.R. 620(a), 12 N.J.R. 75(e). Further amendments were filed and became effective on March 20, 1980 as R.1980 d.123. See: 12 N.J.R. 73(d), 12 N.J.R. 186(c). Further amendments were filed and became effective August 6, 1981 as R.1981 d.296. See: 13 N.J.R. 267(a), 13 N.J.R. 487(b). Further amendments became effective June 6, 1983 as R.1983 d.205. See: 15 N.J.R. 307(b), 15 N.J.R. 920(c). In compliance with Executive Order No. 66(1978), this chapter was readopted effective December 14, 1983 as R.1983 d.604. See: 15 N.J.R. 1708(b), 16 N.J.R. 48(a). Due to the significant changes to this chapter, the Department repealed the existing chapter and adopted a new chapter effective October 7, 1985 as R.1985 d.498. 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).

Chapter 33 was repealed and replaced with new rules, effective September 8, 1992, R.1992 d.342. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS

8:33-1.1 Purpose; 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 to best implement the statutory provisions and

to reflect changing economic and systemic conditions within the health care system.

(b) The Health Care Facilities Planning Act provides that no health care facility shall be constructed or expanded, and no new health care service shall be instituted, except upon application for and receipt of a certificate of need. It further provides that no agency of the State or of any county or municipal government shall approve any grant of funds for, or issue any license to, a health care facility which is constructed or expanded, or which institutes a new health care service, in violation of the provisions of this act, N.J.S.A. 26:2H-7. Finally, the Act states:

“No government agency and no hospital service corporation organized under the laws of the State and no other purchasers of health care services shall purchase, pay for or make reimbursement or grant-in-aid for any health care services provided by a health care facility unless at the time the service was provided, the health care facility possessed a valid license or was otherwise authorized to provide such service.” N.J.S.A. 26:2H-18.

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

Certificate of Need Program
New Jersey State Department of Health
CN 360, Room 604
Health-Agriculture Building
John Fitch Plaza
Trenton, New Jersey 08625-0360
(609) 292-6552

(d) In addition, before filing a certificate of need application, prospective applicants are encouraged to contact the Local Advisory Board (LAB) 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 LAB's plans, the State Health Plan, and appropriate regulations. If the proposed service area overlaps more than one planning region, the applicant should consult with each of the affected LABS.

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

Law Review and Journal Commentaries

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

Case Notes

Regulation revised to comply with minimum requirement for acceptable certificate of need program under federal regulations; regulation valid pertaining to certificate requirement prior to major medical equipment purchase. Radiological Society of New Jersey v. New Jersey State Dept. of Health, 208 N.J.Super. 548, 506 A2d 755 (App.Div.1986), certification denied 104 N.J. 444, 517 A.2d 434.

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 State Department of Health 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 consistent with the health care needs identified in the State Health Plan and the action 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 deemed complete for processing.

(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, rules and policies.

(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. The Commissioner may approve or deny an application for a certificate of need if the approval or denial is consistent with the State Health Plan. If any application is denied, the applicant may appeal the decision to the Health Care Administration Board.

(g) No decision shall be made by the Commissioner contrary to the recommendations of the State Health Planning Board or the local advisory 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. 52:14B-1 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 A.2d 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.

“Adult 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 functionally impaired adult patients exclusively on an outpatient basis.

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

“Applicant” means an individual, a partnership, a 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.

“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.

“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 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.

“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.

"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-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 rule, 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.

"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 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, includ-

ing 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.

"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.

"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, nursing home, intermediate 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 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 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.

“Medically underserved” groups refer to segments of the population which currently fail to use health care services in numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services.

“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.

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

“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 governing community mental health services and State aid under the Community Mental Health Services Act (N.J.A.C. 10:37):

1. Outpatient care: A setting that provides treatment and related services to people who are not in an immediate crisis. Such persons need services that are longer term than those provided by Emergency/Screening. Yet, such services are also less structured than daily or semi-daily involvement in a partial care program;

2. Partial care: A setting that provides three or more hours daily of program involvement to maximize a client's independence and community living skills. Partial care programs provide or arrange for a full range of services necessary to meet the comprehensive needs of individual clients; and

3. Emergency screening: The provision of 24-hour service, seven days a week, to people in crisis. Emergency/screening offers immediate crisis-intervention and service procurement to relieve client distress and maintain or recover his or her level of functioning. Emphasis is on stabilization, so that the client can actively participate in a needs assessment and in service planning.

“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.

“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.

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

“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.

“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.)

“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.

“State Health Planning Board” means the board established pursuant to section 10 of P.L. 1991, c.187, to prepare and review the State Health Plan and to conduct certificate of need review activities.

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

“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).

Case Notes

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

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).

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).

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).

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).

SUBCHAPTER 2. APPLICABILITY OF CERTIFICATE OF NEED REQUIREMENTS

8:33-2.1 Types of review

There will be two types of review of certificate of need applications: full review, as described in N.J.A.C. 8:33-4.1(a), and expedited review, as described in N.J.A.C. 8:33-4.1(b). The full review process applies to all certificate of need applications not specifically identified herein as meeting the criteria for expedited review.

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 need 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, but not be limited to:

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, para-medical 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; and

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.

(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 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 A.2d 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).

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 will 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 State Health Plan or in specific health planning regulations guiding the review of the proposed service or equipment. However, where these standards are not identified in either the State Health Plan or the 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 the principles of P.L. 1991, c.187 concerning access, quality and cost containment.

(d) The satisfaction of (b)1, 2, and 3 above will 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 will not be waived for any health care service proposed to be provided by a physician to inpatients.

3. The certificate of need requirement will 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 will 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 Commissioner 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.S.A. 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 must 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 will 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 will 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 will 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 will 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).

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.

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

8:33-3.2 Termination of service and reduction of 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 require 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 hospital requires a certificate of need and shall follow the full review process. Where a certificate of need is not required pursuant to this section, written notification shall be filed, with the Department's Division of Health Facilities Evaluation and Licensing and with the Certificate of Need Program, 120 days prior to the proposed closure of a facility or discontinuance of all of its services and full compliance with all applicable regulations for closure/discontinuance is 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 in-patient health care facility. In these instances, the licensed entity shall notify the Department's Certificate of Need Program in writing 60 days prior to discontinuance of the service. The Depart-

ment 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(b).

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

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);

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(b);

4. A long-term care facility in which the proposed owner does not satisfy the Department of Health'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 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(b);

5. A physician who initiates a service pursuant to the grandfathering provisions of P.L. 1992, c.187 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(b); and

6. The waived 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.187 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 Licensing Program in the Division of Health Facilities Evaluation and Licensing, 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 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) will 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 of Health 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 must be identified by name, home address and percentage of interest.

(h) The following types of changes by operating health care facilities do not require certificate of need approval by the Department as transfers of ownership, but do require prior written notice to the Division of Health Facilities Evaluation and Licensing 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 Licensure Program, 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 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 sub-chapter and will 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 approved certificates of need prior to licensure 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 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 unlicensed certificate of need

project through foreclosure on a mortgage, lien, or other security interest, the certificate of need ordinarily will be automatically nullified. However, 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 must 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.

(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 can waive this requirement where he or she determines 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).

8:33-3.4 Bed capacity, medical day care slot capacity

(a) The following criteria apply to changes in bed capacity:

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 process, except 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 Division of Health Facilities Evaluation and Licensing for authorization pursuant to N.J.S.A. 26:2H-7.2.

ii. Establishment of a residential health care facility requires a certificate of need and shall follow the expedited review process set forth in N.J.A.C. 8:33-4.1(b). Any increase or decrease in the bed complement of an existing licensed residential health care facility and any capital expenditures exclusively associated with the bed changes are exempt from the certificate of need requirement. However, approval from the Department's Health Facilities Construction Services prior to building construction or renovations, and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation prior to implementation of the bed changes are required, in accordance with this chapter and the Department's licensing rules.

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 will 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 will 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 will 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 will be required to notify in writing by certified mail the Certificate of Need Program and the Division of Health Facilities Evaluation in the State Department of Health 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 will 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 from one physical facility or site to another requires a certificate of need and shall follow the expedited review process, except that if the relocation is from one county to another, the application shall follow the full review process.

(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 does not require a certificate of need. However, approval from the Department's Health Facilities Construction Services prior to building construction or renovations and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation 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).

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 and shall follow the full review process 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;

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 is exempt from the certificate of need requirement providing it 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 Licensing Program in the Division of Health Facilities Evaluation;

iii. All direct patient services in the existing facility will 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 will be required and will follow the full review process.

3. Establishment of a satellite location for a primary care center by an existing health care facility does not require a certificate of need. In these instances the licensed entity will be required to notify the Department's Licensing Program in the Division of Health Facilities Evaluation in writing prior to establishment of a satellite location. If the Department determines that the proposed facility is not a satellite as defined herein, the facility will require a certificate of need which shall follow the full review process. The Department's final determination regarding whether a proposed facility qualifies as a satellite location in accordance with N.J.A.C. 8:25, or the establishment of a new health care facility will be a final agency decision.

4. 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 Department's Health Facilities Construction Services, in accordance with the Department's licensing rules, prior to building construction or renovations and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation, in accordance with the Department's rules, prior to operation and occupancy of the beds, service or facility; and

5. Relocation of a component service of an existing health care facility will not require a certificate of need where the relocation will not result in problems of access to populations historically served and the service is not a service which is required to be a component of an inpatient health care facility. In these instances the licensed entity will be required to notify the Department's Certificate of Need Program in writing prior to relocation of the service. The Department will notify the provider whether the proposed relocation requires a certificate of need which shall follow the expedited review process in accordance with N.J.A.C. 8:33-4.1.

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

8:33-3.6 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 and shall follow the full review process 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). 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. If the equipment replacement or renovations are not mandatory, a certificate of need will

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 Department's Health Facilities Construction Services prior to building construction or renovations and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation 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).

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 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;
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) Mandatory replacement of major moveable equipment as defined at N.J.A.C. 8:33-1.1, is 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. If the equipment replacement is not mandatory, a certificate of need will be required and shall follow the full review process, in accordance with N.J.A.C. 8:33-6.1.

(f) Acquisition, replacement, expansion, or transfer of major moveable equipment which is exempt from the certificate of need requirement requires approval from the Department's Health Facilities Construction Services prior to building construction or renovations and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation 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).

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 change in the cost of an approved project shall require a change of cost review and shall follow the expedited review process outlined in N.J.A.C. 8:33-5, except as follows:

1. A certificate of need for change in cost for an original certificate of need approval issued after September 8, 1992 may not exceed 10 percent of the approved capital cost plus any construction cost factor calculated by the Department for the life of the certificate of need. Any certificate of need application for change in cost which exceeds 10 percent will not be accepted for processing.

2. A certificate of need for change in cost for an original certificate of need approval issued prior to the effective date of these rules may be filed regardless of the amount of the increase in cost.

3. 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 project 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 approved, but unimplemented, certificate of need project:

1. Relocation of the proposed project within the same county does not require a certificate of need review. The applicant shall submit written notification to the Certificate of Need Program and the Division of Health Facilities Evaluation with appropriate documentation of site control. Relocation of a proposed project which is exempt from the certificate of need requirement requires approval from the Department's Health Facilities Construction Services prior to building construction or renovations and approval from the Department's Licensing Program in the Division of Health Facilities Evaluation 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 will not be accepted for processing. Failure of the applicant to implement the project within the same county will result in nullification of the approved certificate of need.

(c) The following criteria shall apply to changes in square footage:

1. Any increase 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 project costs and would be subject to the criteria identified at (a) above.

2. Any decrease of less than 10 percent of the total approved square footage to be renovated and/or constructed does not require a certificate of need.

3. Any decrease of 10 percent or greater of the total approved square footage to be renovated and/or constructed with a commensurate reduction in cost requires a certificate of need and shall follow the expedited review process. An application for a decrease in square footage of 10 percent or greater without a commensurate reduction in cost will not be accepted for processing.

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

1. A certificate of need for change in scope for an original certificate of need approval issued prior to September 8, 1992 may be filed providing that the scope change results in a reduction of beds, elimination of approved major moveable equipment or elimination of services and shall follow the expedited review process. All applications for change in scope must be filed with the Department no later than December 31, 1993. Applications filed after that date will not be accepted for processing.

2. The Department will not accept for processing the following changes in scope for an original certificate of need approval issued prior to September 8, 1992. Failure to implement the scope of the project as approved will result in nullification of the approved 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;
- 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 will not accept for processing the following changes in the scope of any approved certificate of need. Failure to implement the scope of the project as approved will result in nullification of the approved 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) The Department will not accept for processing any change in scope for an original certificate of need approval issued after September 8, 1992 unless the change is for the exclusive purpose of reducing the scope of the project with a commensurate reduction in cost. Failure to implement the scope of the project as approved will result in nullification of the approved certificate of need and require the filing of a new certificate of need application in the next appropriate cycle.

(g) Any change in financing or change in the method of financing which will 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 will 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 will, 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.

(h) Any modifications to the project as approved shall be reported to the Department's Certificate of Need 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).

8:33-3.10 Duration of 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. Under exceptional circumstances, the Commissioner may grant additional time in the initial certificate of need approval letter for completion of a project. The applicant will be required to petition for the extended period of time in its application, providing a detailed schedule for project implementation and identifying a specific time frame for project completion.

- i. If the project has not been approved and/or licensed by the Department's Division of Health Facilities Evaluation and Licensing 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 exam-

ple, 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.

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. The applicant will be required to file for an extension of time 60 days prior to the current expiration and to propose a detailed time frame identifying the remaining time needed to complete the approved subject. Where the Commissioner determines that the approval should be extended for an additional period of time beyond its current expiration date, he or she will assign a final expiration date.

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

8:33-3.11 Demonstration and research projects

(a) (Reserved)

(b) 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.

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

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

SUBCHAPTER 4. THE REVIEW PROCESS

Law Review and Journal Commentaries

Certificates of Need—Appeals. P.R. Chenoweth, 138 N.J.L.J. No. 14, 72 (1994).

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 of Health. The full review process for certificate of need applications will 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 major newspapers of general circulation in the State. The notice will also be distributed to health care associations on file with the Department, filed with the Office of Administrative Law and published in the New Jersey Register. Beginning in calendar year 1993 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 during 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. 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, 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. A decision should generally be rendered by the Commissioner approximately three months after the application is deemed complete for processing.

(b) The expedited review process involves review of a certificate of need application by the Department of Health. 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 fifteenth day of each month and a decision should generally be rendered by the Commissioner approximately two months after the application is deemed complete for processing. Deadlines for initial submission of applications for expedited review shall be no later than the first day of the month preceding the beginning of a review cycle.

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).

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).

8:33-4.2 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 will 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, may 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 Program
 New Jersey State Department of Health
 CN 360, Room 604
 John Fitch Plaza
 Trenton, New Jersey 08625-0360
 (609) 292-6552

(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 review or full review process. Fees shall be paid in full at the time applications are filed with the Certificate of Need Program. Failure to pay the appropriate application filing fee in full shall form a sufficient basis to deem the application to be incomplete. 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 unrespon-

sive to the notice issued by the Commissioner or inappropriately requests expedited review, it may be declared not accepted for processing by the Department, in which case the filing fee will be returned.

Total Project Cost (TPC)	Fee Required
\$1,000,000 or less	\$ 5,000
Greater than \$1,000,000 but less than \$10,000,000	\$ 5,000 + 0.05% of TPC
\$10,000,000 or greater	\$100,000
Transfer of ownership	\$ 5,000
Change in Cost/Scope	\$ 5,000

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 must 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 is 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 will be hired, the name and address of all principals in the management company shall be identified and, if the certificate of need is approved, prior to licensure, a copy of the management agreement shall be submitted to the Certificate of Need Program and the Division of Health Facilities Evaluation and Licensing. Any change in management subsequent to certificate of need approval shall be reported to the Division of Health Facilities Evaluation and Licensing.

(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 above provisions, the Department will determine the application to be incomplete.

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 must provide the Department with written comments 20 days after the application filing deadline. The Department will 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 LAB. The Department will make a decision on the completeness by the beginning of each review cycle and will notify both the applicant and the affected local advisory board(s) of its determination. Only complete applications will 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 will 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 accepted for processing by the Department. The Department will notify the applicant of this decision and the filing fee will be returned.

(c) Once an application has been submitted to the Department of Health, no subsequent submission of information will 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 must 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) must 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.

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, will 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 will 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 must 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 will 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 will 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) The State Health Planning Board shall prepare and revise annually a State Health Plan. The State Health Plan shall identify the unmet health care needs in an area by service and location and it shall serve as an advisory document which may be considered when certificate of need applications are reviewed for approval. The State Health Planning Board shall consider the recommendations of the local advisory boards in preparing and revising the plan to incorporate specific regional and geographic considerations of access to, and delivery of, health care services at a reasonable cost. The State Health Planning Board shall incorporate the recommendations of the local advisory boards into the plan unless the recommendations are in conflict with the best interests of Statewide health planning. If any recommendations of the local advisory boards are not incorporated into the plan, the State Health Planning Board shall identify those recommendations, which shall be listed separately for each local health planning region, in an addendum to the plan and shall state the specific reason that each recommendation is in conflict with the best interests of Statewide health planning.

(b) 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, 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:

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 of Health.

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

(d) No certificate of need shall be granted to any facility that currently fails to provide or fails to contractually commit to provide services to medically underserved 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.

(e) For the three-year period beginning January 1, 1992 through December 31, 1994, the Commissioner shall limit approval of certificates of need for hospitals for capital construction projects that would be financed by the New Jersey Health Care Facilities Financing Authority to a Statewide total of \$225,000,000 per year for all projects, exclusive of the refinancing of approved projects.

1. "Capital construction project" shall include the purchase of major moveable equipment, as well as any modernization, construction or renovation project.

2. The annual cap shall include the total project cost of each approved certificate of need for acute care hospitals including the following:

i. All amounts approved for all applicable projects submitted prior to the current certificate of need moratorium but not acted on before January 1, 1992;

ii. All capital construction projects, including all those that are or would be financed by the Health Care Facilities Financing Authority. These may include projects that are financed partially through hospital equity or a source other than the Health Care Facilities Financing Authority, if the project is deemed eligible for such financing by the Authority;

iii. The cap shall not apply to a certificate of need application for a change in cost to a project originally approved prior to January 1, 1992; and

- iv. The cap shall not apply to a certificate of need application which is funded totally by cash equity.
- 3. Approvals of certificate of need applications within the annual \$225,000,000 shall permit approval of projects in the following two categories:
 - i. Construction/renovation/modernization: Approvals in this category may total up to \$205,000,000;
 - ii. Major Moveable Equipment: Approvals in this category may total up to \$20,000,000;
 - iii. In any year where the full allocation within the above amounts is not awarded through certificate of need actions by the Commissioner, projects of the remaining category may be approved.
- 4. The annual cap shall apply to the year in which the certificate of need applications are received.

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

8:33-4.10 Specific criteria for review

(a) Each applicant for a certificate of need must show how the proposed project will 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 underserved 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 underserved 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 underserved, and the extent to which medically underserved 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 underserved 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 CFR 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 will address otherwise unmet needs in a particular municipality, county, and/or regional health planning area; that it will 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 will 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 will 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 will 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 underserved population;

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

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

7. Each applicant for certificate of need must demonstrate how the proposed project will 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 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 will 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-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 and Hospitals 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 certificate of need extending to the date the Commissioner issues a final decision, 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, by evidence of any continuing violation or a pattern of violations of State licensing standards or Federal certification standards at any health care facility in which the applicant has or has had an ownership or managerial interest. 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 Chapter, includes any person, partner, and/or corporation which is an owner, principal, operator or manager of the proposed or existing licensed health care facility which is seeking certificate of need approval;

4. A certificate of need submitted by an applicant who was cited for any State licensing or Federal certification deficiency during the period identified in (e)3 above, which represented a serious risk to the life, safety, or quality of care of the facility's patients or residents, shall be denied. 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 in the areas of nursing, patient rights, patient assessment of care plan, dietary services, infection control and sanitation, or pharmacy resulting in:

- i. An action by a State or Federal agency to curtail or temporarily suspend admissions to a facility; or
- ii. In the case of long term care, a finding of two or more Level A violations as a result of one survey, or one or more Level A violations of the same type on consecutive surveys;

5. In evaluating track record pursuant to (e)3 or 4 above, the Department may consider any evidence of noncompliance with applicable licensure requirements provided by an official state licensing agency in any state outside of New Jersey, or any official records from any agency of the State of New Jersey indicating the applicant's non-compliance with the agency's licensure or certification requirements in a facility the applicant owned, operated, or managed in whole or in part.

6. 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 period of at least one year has elapsed, during which time the person must have demonstrated a record of continuous 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

7. 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. Furthermore, no certificate of need application will be accepted for processing if it is possible for the Department to determine the unacceptability of the applicant's track record. An exception will be 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).

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 for incorporation into the State Health Plan.

(b) The local advisory board shall review certificate of need applications for proposed projects in its region and make recommendations to the Commissioner in consideration of the State Health Plan and 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; and
3. Evaluation of the public need for each proposal in consideration of the State Health Plan, 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 regulations.

(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 Departmental 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).

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 consideration of the State Health Plan and in accordance with all applicable health planning regulations.

(b) 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.

(c) 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 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.

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

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.

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).

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 of Health for his or her review.

(c) If an application which is consistent with the State Health Plan 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 of Health 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 will be forwarded to the Office of Administrative Law where it will 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 LAB or SHPB. 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 will be the final decision.

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

5. The process will 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).

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 of Health review

(a) The Commissioner may approve or deny an application for a certificate of need upon consideration of the State Health Plan and 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 will 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 recommends denial of 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 recommendations of the State Health Planning Board or the Local Advisory 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 approved 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 must 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.

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 approved certificate of need conditions 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 will 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 will 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 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 approved 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 residential health care facilities;
2. Establishment of a restricted admissions facility or change in bed capacity of a restricted admissions facility;
3. Change in cost to an original certificate of need issued after September 8, 1992 which is 10 percent or less of the approved capital cost including an inflation factor;
4. Change in cost to an original certificate of need issued prior to September 8, 1992; and
5. Establishment of or changes in the capacity of comprehensive personal care homes, in accordance with the requirements of this chapter and the Department's licensing rules;

(b) The expedited review process may also be used in lieu of the full 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.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

8:33-5.2 Process

(a) The expedited review process will include 12 review cycles. The beginning of each cycle shall be the 15th day of each month and a decision should be rendered by the Commissioner approximately two months after the application is deemed complete for processing. Deadlines for initial submission of applications for expedited review shall be no later than the first day of the month preceding the beginning of a review cycle.

(b) Applications will be reviewed to determine the completeness of the required information. The Department shall make a determination by the beginning of the cycle as to whether the application is complete for processing.

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

(d) 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 complete for processing.

(e) Certificate of need application forms for expedited review (except transfer of ownership) may be obtained from, and 10 copies shall be filed with:

Certificate of Need Program
 New Jersey State Department of Health
 John Fitch Plaza
 CN 360, Room 604
 Trenton, New Jersey 08625
 (609) 292-6552

(f) Certificate of need application forms for expedited review for transfers of ownership may be obtained from, and 10 copies shall be filed with:

Health Facilities Evaluation
 New Jersey State Department of Health
 CN 367
 Trenton, New Jersey 08625
 (609) 588-7791

(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 capital cost, operating costs and revenues, square footage, services affected, equipment involved, source of funds, utilization statistics, both inpatient and outpatient, how the project will foster economies within patient charge structure and justification for the proposed project;
2. The extent to which all residents of the area will have access to services, particularly the medically underserved; and
3. Assurances by the applicant, that all appropriate access criteria identified at N.J.A.C. 8:33-4.9 and 4.10 will be met.

8:33-5.4 Specific requirements

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

1. For a change in cost, scope or financing, a description of new project costs by category, new square footage and new financing alignment;

2. For a change in beds, the number of beds to be added or deleted, a description of service area, required changes in staffing patterns, assurances that the impact on existing and approved facilities will foster optimum utilization and factors affecting travel time in area and availability of health personnel supply for staffing, and explanation of beds by service, the services affected, and the total number of beds available at the completion of the project; or

3. For a transfer of ownership, identification of all major licensure deficiencies and date of violation for any health care facility for any applicant (including any principals thereof) who owns (in whole or in part), manages or operates or has owned (in whole or in part) managed, or operated any health care facility, especially:

- i. Curtailment of admissions; and
- ii. A record of non-compliance with State licensure standards (N.J.A.C. 8:39) or comparable Federal, Medicare and Medicaid certification requirements.

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

8:33-5.5 (Reserved)

Repealed by R.1993 d.442, effective September 7, 1993.
 See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
 Section was "Required commitments for the medically underserved".

APPENDIX

Exhibits Historical Note

Former Exhibit 1, Health Service Areas for the State of New Jersey; Exhibit 2, Health Systems Agencies in New Jersey; Exhibit 3A, Standard Categories of Health Care Services; and Exhibit 3B, Health Care Services within the Standard Categories, were repealed by R.1993 d.442, effective September 7, 1993. See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

EXHIBIT 1

LOCAL ADVISORY BOARDS IN NEW JERSEY

Region	Name of Agency	Counties Served
I	Region One/Health Planning Consortium	Morris Passaic Sussex Warren
II	Fairleigh Dickinson University	Bergen Hudson
III	Region III Local Advisory Board	Essex Union
IV	Midstate Health Advisory Corp.	Hunterdon Mercer Middlesex Somerset

Region	Name of Agency	Counties Served
V	HealthVisions, Inc.	Burlington Camden Cumberland Gloucester Salem
VI	Jersey Coast Health Planning Council, Inc.	Atlantic Cape May Monmouth Ocean

Recodified from 8:33-5 by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

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

B. Non-bed related

1. Home health agency
2. Comprehensive outpatient rehabilitation facility
3. Surgical facility
4. Special child health clinics providing tertiary services

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. Positron emission tomography services

11. Magnetic resonance imaging and nuclear magnetic resonance services
12. Extracorporeal shock wave lithotripsy services
13. Birthing centers
14. Comprehensive personal care home
15. Assisted living residence
16. Bone marrow transplant/harvesting
17. Trauma services
18. Children's hospitals
19. Hyperbaric chambers
20. Emergency medical service helicopters
21. Central service agency
22. Any service for which regionalization criteria or health planning regulations have been developed.
23. Other new health/medical care technologies including any medical equipment which has received FDA pre-marketing approvals.

Recodified from 8:33-5 and amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

EXHIBIT 2a

HEALTH CARE SERVICES WITHIN THE STANDARD CATEGORIES

Repealed by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
Was codified at 8:33-5.

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 (NMR) and magnetic resonance imaging (MRI) equipment
- Positron emission tomography (PET)

Recodified from 8:33-5 by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).

SUBCHAPTER 6. CERTIFICATE OF NEED EXEMPTIONS

Source and Effective Date

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

Subchapter Historical Note

Subchapter 6, formerly Certificate of Need Moratorium, was repealed by R.1993 d.442 and new rules were adopted. See: Source and Effective Date.

The following rulemakings occurred in the former Subchapter 6:

Emergency New Rule, R.1991 d.474, effective August 22, 1991 (expires October 16, 1991).

See: 23 N.J.R. 2881(a).

Amended by R.1991 d.566, effective November 18, 1991.

See: 23 N.J.R. 2881(a), 23 N.J.R. 3512(a).

Provisions of Concurrent Proposal adopted.

Amended by R.1992 d.172, effective April 20, 1992.

See: 24 N.J.R. 173(a), 24 N.J.R. 1496(a).

Department accepts CN applications for services listed in (b)6-14 during moratorium.

Recodified by R.1992 d.342, effective September 8, 1992.

See: 24 N.J.R. 2222(a), 24 N.J.R. 3104(a).

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 of Health'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 (USC 483.1 through 483.158).
9. Change of site for an approved 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 will 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 purchase 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.

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 of Health for a determination prior to proceeding with the replacement or renovations.

(c) For community-based primary care 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 of Health 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 of Health prior to licensure of the long-term care beds.

(e) Written notification and architectural plans shall be submitted to the Department's Health Facilities Construction Services 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 Licensing Program in the Division of Health Facilities Evaluation 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 Department's Licensing Program in the Division of Health Facilities Evaluation for approval prior to any transfer of ownership of beds, service or facility, in accordance with this chapter and the Department's licensing rule.