

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

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

(f) Certificates of need shall be issued by the Commissioner based upon criteria and standards promulgated by the Commissioner and the State Health Planning Board and approved by the Health Care Administration Board. (See N.J.A.C. 8:33 and the applicable chapter for specific services.) If any application is denied, the applicant may appeal the decision to the Health Care Administration Board, in accordance with N.J.S.A. 26:2H-9.

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

Case Notes

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

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

8:33-1.3 Definitions

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

“Accepted for processing” means that the application has been fully and accurately filled out and signed by the applicant, that all track record reports, appendices and application fees required by this chapter have been submitted at the time of filing, and that the application has been entered into the applicable expedited review cycle.

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

“Adult day health care facility” means a facility which is licensed by the Department to provide preventive, diagnostic, therapeutic, and rehabilitative services under medical

supervision to meet the needs of functionally impaired adult patients exclusively on an outpatient basis.

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

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

“Alternate family care program” means a program operated by a community-based agency institution, facility, or private entity which is responsible for recruiting, screening, training, and supervising alternate family caregivers, as well as matching clients with alternate family caregivers and monitoring client status within this arrangement.

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

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

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

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

“Applicant” means an individual, a partnership, a corporation (including associations and joint-stock companies), a state, or a political subdivision or instrumentality (including a municipal corporation) of a state that will be the licensed operator of the proposed service, facility or equipment,

which will have overall responsibility for the health care service to be provided.

“Assisted living program” means the provision of, or arrangement for, meals and assisted living services, when needed, to the tenants (also known as residents) of publicly subsidized housing which because of any Federal, State, or local housing laws, regulations or requirements cannot become licensed as an assisted living residence in accordance with N.J.A.C. 8:36. An assisted living program may also provide staff resources and other services to a licensed assisted living residence and a licensed comprehensive personal care home.

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

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

“Birth center” means an ambulatory care facility or a distinct part of a health care facility which is separately licensed as an ambulatory care facility which provides routine prenatal and intrapartum care. These facilities provide care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth.

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

“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, 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” means a deviation from the unimplemented 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 New Jersey State Commissioner of Health and Senior Services.

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

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

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

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

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

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

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

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

"Continuing care retirement community" means the provision of lodging and nursing, medical or other health related services at the same or another location to an individual pursuant to an agreement effective for the life of the individual or for a period greater than one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without other periodic charges. A fee which is less than the sum of the regular periodic charges for one year of residency is not considered an entrance fee. For certificate of need exemption purposes, a new or proposed community which will have fewer than four independent living units per nursing facility bed, or an existing community which proposes to

construct additional nursing facility beds which will be utilized by persons who have not paid the entrance fee, is not a continuing care retirement community. The required four to one ratio shall be maintained at all times. Beds licensed as assisted living residence, comprehensive personal care home or residential health care may be counted in the numerator of this ratio, at the discretion of the applicant.

"Deemed complete for processing" means an application has been determined to be complete by the Department and has been entered into the applicable direct or full review cycle.

"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 and Senior Services.

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

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

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

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

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

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

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

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

"Hospital-based subacute care unit" means a unit located within an acute care general hospital which utilizes licensed long-term care beds to provide subacute care.

"Invalid coach service" means the provision of nonemergency 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 nonprofit corporation established pursuant to N.J.S.A. 26:2H-5.9, which is not a health care facility, a subsidiary thereof or an affiliated corporation of a health care facility, that is designated by the Commissioner 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” means segments of the population whose utilization of health care services is less than those numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services. Medically underserved may include, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

“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.

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

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

“Nonbed related outpatient psychiatric care” means the following, which, to be considered a health care service, must meet standards as prescribed by the rules of the Department of Human Services governing community mental health services and State aid under the Community Mental Health Services Act.

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

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

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

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

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

“Operating revenues” means total operating revenues from the hospital’s most recent year audited financial statements, which will be inflated using a global economic factor, as defined in N.J.A.C. 8:31B, which measures the change in the prices of goods and services used by New Jersey hospitals.

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

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

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

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

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

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

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

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

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

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

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

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

"Provider of health care" means an individual:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“Service area” means a geographic area, generally a county, within which the facility or service is located. More specific definition is found in the Department’s rules for specific services.

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

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

“State Health Planning Board” means the board established pursuant to N.J.S.A. 26:2H-5.7 to conduct certificate of need review activities.

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

“Subacute care in a general acute care hospital” means a comprehensive in-patient program for patients who have had an acute illness, injury or exacerbation of a disease process, have a determined course of treatment prescribed, and do not require intensive diagnostic or intensive invasive procedures. A subacute care patient’s condition requires physician direction, intensive nursing care, frequent recurrent patient assessment and review of the clinical course and treatment plan for a period of time, significant use of ancillary medical services and an interdisciplinary approach using professional teams of physicians, nurses and other relevant professional disciplines to deliver complex clinical interventions.

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

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

1. At least two rooms dedicated for use as operating rooms which are specifically equipped to perform surgery. These rooms are designed and constructed to accommodate invasive diagnostic and surgical procedures; and
2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged.

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

1. One room dedicated for use as an operating room which is specifically equipped to perform surgery. This room is designed and constructed to accommodate invasive diagnostic and surgical procedures;
2. One or more postanesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and
3. Established by a physician or physician professional association surgical practice solely for his/her/their private medical practice.

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

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

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

“Unimplemented certificate of need” means that the facility or service for which the certificate of need was approved has not yet been licensed by the Department’s Certificate of Need and Acute Care Licensure Program or Long-Term Care Licensing and Certification Program, as applicable. A certificate of need ceases to exist at the point at which it is implemented (that is, when the license becomes effective). All certificate of need conditions of approval travel with the license.

"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 and no further consideration or review shall be given to the "withdrawn" application.

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

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

1. The types of health care service and facilities, and changes thereto, which are required to obtain certificate of need approval by the provisions of this subchapter;
2. The type of health care service delivered or to be delivered, its impact on existing health care facilities and providers and its potential effect on the health care delivery system;
3. The apparent costs of equipping, staffing and operating the health care service and the resultant cost to all payors and consumers of health care;
4. The degree of complexity in terms of medical technology, equipment, and the medical, paramedical and administrative staffing required to provide the health care service;
5. The evaluation of how historically established referral patterns will be impacted upon by the proposed service;
6. The financial arrangements for the payment or reimbursement of health care services available to both the service entity in question and to those persons receiving such care; and
7. Any other factors specific to the unique circumstances of an individual applicant.

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

SUBCHAPTER 2. APPLICABILITY OF CERTIFICATE OF NEED REQUIREMENTS

8:33-2.1 Types of review

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

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

Case Notes

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

Regulations reflect concern over those aspects of health care that relate to patient access as well as personnel policies affecting patient care. *Desai v. St. Barnabas Medical Center*, 103 N.J. 79, 510 A.2d 662 (1986).

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

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

Law Review and Journal Commentaries

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

Case Notes

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

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

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

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

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

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

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

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

8:33-4.15 Procedures for Commissioner review

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

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

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

(d) After the commencement of a fair hearing pursuant to (c) above, and before a decision is made, there shall be no ex parte contacts between any person acting on behalf of

the applicant or holder of a certificate of need, or any person opposed to the issuance of a certificate of need, and any person in the Department who exercises any responsibility for reviewing the application. Ex parte communication is defined as an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given. It shall not include requests for status reports on any matter or proceeding. Any communications made after commencement of the fair hearing that are placed in the record of the proceedings are made available to all parties are not ex parte and are not prohibited.

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

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

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

Case Notes

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

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

8:33-4.16 Conditions on approval/monitoring

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

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

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

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

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

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

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.1 Statement of purpose

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

1. Establishment of a residential health care facility;
2. Establishment of a Statewide restricted admissions facility or change in bed capacity of a Statewide restricted admissions facility;

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

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

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

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

7. Establishment of a birth center;

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

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

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

11. Establishment of a comprehensive outpatient rehabilitation facility;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8:33-5.2 Process

(a) The expedited review process shall include 12 review cycles. The beginning of each cycle shall be the first business day of each month and a decision shall be rendered by the Commissioner no later than 90 days thereafter. Applications received after the first business day of the month shall be processed in the next month's cycle.

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

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

(d) Certificate of need applications subject to expedited review shall be reviewed in accordance with the require-

ments of this chapter, the Department's licensing rules and applicable health planning rules.

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

(f) Certificate of need application forms for expedited review may be obtained from the Department at the address listed below. Applicants should contact staff of the Certificate of Need and Acute Care Licensure Program before filing an application to be certain that they have a copy of the most recent version of the Department's application. Applications other than the Department's most recent version shall not be accepted for processing. An original and 10 copies of the application shall be filed with:

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

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

8:33-5.3 General requirements

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

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

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

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

- i. Appropriate licensing and construction standards;
- ii. Licensure track record requirements (N.J.A.C. 8:33-4.10(e)); and
- iii. Financial information that includes the impact of the proposed project on the provider's financial condition, as measured by financial statements, including balance sheets, income statements and cash flow statements.

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

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

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

8:33-5.4 Specific requirements

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

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

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

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

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

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

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

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

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

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

3. For a hospital-based subacute care unit:

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

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

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

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

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

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

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

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

SUBCHAPTER 6. CERTIFICATE OF NEED EXEMPTIONS

8:33-6.1 Statement of purpose

(a) In accordance with the provisions of the Health Care Reform Act, P.L. 1992, c.160, the following specific health care services or projects are exempt from the certificate of need requirement:

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

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

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