

(c) Once an application has been submitted to the Department, no subsequent submission of information shall be accepted, unless specifically requested in writing by the Department, the State Health Planning Board or the local advisory board(s). Any questions and subsequent responses shall be forwarded by the State Health Planning Board or the local advisory board(s) to the Department on a timely basis.

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

Case Notes

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

8:33-4.6 Modification of applications

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

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

8:33-4.7 Deferral of applications

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

(b) The local advisory board, the State Health Planning Board, or the Department may defer an individual certificate of need application where the application is not competitive or comparatively reviewed with other applications. Where projects are competitive or comparatively reviewed, the local advisory board, the State Health Planning Board, or the Department may defer the entire batch. In the case of an application or batch of applications proposed for more than one local advisory board planning region, one local advisory board may not defer without concurrence of all other local advisory boards reviewing the application or batch of applications. In the instance of projects which are

the subject of a capital cap, only the Commissioner may defer any or all applications in the batch. The State Health Planning Board may recommend deferral of the entire capital batch to the Commissioner. The basis for any deferral shall be specified in writing to the applicant. The period of deferral of an individual certificate of need application or a batch of certificate of need applications may not exceed six months.

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

1. Reactivated applications with no changes or with only a change in cost may continue in the review process from the point of deferral unless the applicant is required to submit new information in response to a change in the applicable requirements.

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

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

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

8:33-4.8 Withdrawal of applications

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

8:33-4.9 General criteria for review

(a) No certificate of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, shall not have an adverse economic or financial impact on the delivery of health care services in the region or Statewide, and shall contribute to the orderly development of adequate and

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

1. The availability of facilities or services which may serve as alternatives or substitutes;
2. The need for special equipment and services in the area;
3. The possible economies and improvement in services to be anticipated from the operation of joint central services;
4. The adequacy of financial resources and sources of present and future revenues;
5. The availability of sufficient manpower in the several professional disciplines; and
6. Other applicable requirements which are specified in any health planning rule adopted by the Department.

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

(c) No certificate of need shall be granted to any facility that, during the course of the application process, fails to provide or fails to contractually commit to provide services to medically 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.

Amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Case Notes

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

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

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

8:33-4.10 Specific criteria for review

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

1. The contribution of the proposed service in meeting the health related needs of members of medically 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 C.F.R. 124.501 et seq.;

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

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

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

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

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

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

3. Physician and professional staffing issues;

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

5. Provider's historical and projected market shares;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. A certificate of need application submitted by an applicant who was cited for any State licensing or Federal certification deficiency during the period identified in (e)3 above, which presented a serious risk to the life, safety, or quality of care of the facility's patients or residents, shall be denied, except in cases where the applicant has owned/operated the facility for less than 12 months and the deficiencies occurred during the tenure of the previous owner/operator. In any facility, the existence of a track record violation during the period identified in (e)3 above shall create a rebuttable presumption, which may be overcome as set forth below, that the applicant is unable to meet or surpass licensing standards of the State of New Jersey. Those applicants with track record violations which would result in denial of the application shall submit with their application any evidence tending to show that the track record violations do not presage operational difficulties and quality of care violations at the facility which is the subject of the application or in any other licensed long term care category facility in New Jersey, which is operated or managed by the applicant. If, after review of the application and the evidence submitted to rebut a negative track record, the Commissioner denies the application, the applicant may request a hearing which will be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law. The purpose of the hearing is to provide the applicant with the opportunity to present additional evidence in conjunction with evidence already included with the initial application, for the purpose of demonstrating the applicant's operational history and capacity to deliver quality of care to patients or residents which meets or surpasses licensing standards of the State of New Jersey to the satisfaction of the Commissioner or his or her designee. The conclusion of that process with either a decision by the Commissioner or the Commissioner's acceptance or denial of an initial decision by an administrative law judge shall constitute a final agency decision. A serious risk to life, safety, or quality of care of patients or residents includes, but is not limited to, any deficiency in State licensure or Federal certification requirements (42 C.F.R. 488.400 et seq.) resulting in:

- i. An action by a State or Federal agency to ban, curtail or temporarily suspend admissions to a facility or to suspend or revoke a facility's license;
- ii. A decertification, termination, or exclusion from Medicaid or Medicare participation, including denial of payment for new admissions, imposed by the Department or by the Health Care Financing Administration, as a result of noncompliance with Medicaid or Medicare conditions of participation.

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

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

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

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

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

6. The criteria for denial of an application specified in (e)4 and 5 above shall also result in denial of the applica-

tion if the criteria are found to have been true of any number of out-of-State facilities operated or managed by the applicant, within the 12 months preceding submission of the application and extending to the date on which the Commissioner renders a decision with respect to the application and with respect to any service which is similar or related to the proposed service, constituting at least five percent of all facilities operated or managed by the applicant or five facilities in total, whichever is less.

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

i. The scope and severity of the threat;

ii. The frequency of occurrence;

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

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

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

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

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

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

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

iii. The ambulatory care and other category, which includes primary care, home health care, family planning, drug counseling, abortion, ambulatory surgery, and outpatient rehabilitation.

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

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

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

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

Amended by R.1993 d.442, effective September 7, 1993.
See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
Amended by R.1996 d.101, effective February 20, 1996.
See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Case Notes

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

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

8:33-4.11 Notification of review cycles

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

8:33-4.12 Functions of local advisory boards

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

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

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

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

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

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

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

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

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

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