

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

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

(e) The Commissioner may issue a call for demonstrations, not specifically identified in this section.

1. Such call will be activated upon public notice by the Commissioner inviting certificate of need applications for the specific service and published in the New Jersey Register no less than 45 days prior to the date the application is required to be filed.

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

i. Documentation of exactly what is proposed to be demonstrated;

ii. Patient care policies used as part of the demonstration, including criteria for inclusion/exclusion in the demonstration;

iii. Proposed staff and staff qualifications for the demonstration;

iv. Written documentation that otherwise eligible patients will be accepted into the demonstration regardless of ability to pay;

v. Documentation of what data will be collected to evaluate the demonstration project; and

vi. Written assurances that all data collected to evaluate the demonstration project shall be reported to the Department in accordance with requirements specified by the Department.

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

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

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

i. All applicants for demonstrations shall be notified in writing by the Department as to whether they shall be permitted continued operation of the service that is the subject of the demonstration within 60 days of the expiration date of the demonstration license;

ii. Where the Department denies continuance of the demonstration project past the originally approved deadline, as set forth in (e)4 above, the demonstration project shall cease operating not later than 30 days after receipt of the written denial notice by the Department. Operators of denied demonstration projects shall have the right to appeal the Department's denial. A Notice of Appeal shall be sent to the Department within 30 days of receipt of the Department's denial notice. The appeal process shall comply with the requirements set forth in the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

6. All applicants, through a resolution of its Board of Directors, shall acknowledge and accept the standards and criteria set forth for the demonstration as conditions of approval and agree to be bound thereto.

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

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

Inserted (a) and (b).

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

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

Added (d).

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

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

Rewrote the section.

Public Notice: Certificate of Need and Acute Care Licensure.

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

SUBCHAPTER 4. THE REVIEW PROCESS

8:33-4.1 Review cycles and submission dates

(a) The full review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The Commissioner shall publish in the New Jersey Register in February of each year an anticipated schedule for receipt of certificate of need applications subject to full review procedures for a two-year period, including the current calendar year. The Commissioner may announce additional or special calls for certificate of need applications beyond those identified in the yearly notice or may delete announced calls from the yearly notice.

Changes to the published schedule shall be published in the New Jersey Register. Wherever practical, the Commissioner shall provide notice in accordance with this section to allow for a minimum of 90 days between the date of publication of the Commissioner's notice inviting certificate of need applications and the date for submission of applications in response to the notice(s). The notice shall identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, and the date the application is deemed complete for processing. The State Health Planning Board shall forward recommendations to the Commissioner within 90 days after the application is deemed complete for processing unless a fair hearing is requested by an applicant in accordance with the procedures identified at N.J.A.C. 8:33-4.14. For batches with fewer than 20 applications, a final agency decision will be rendered by the Commissioner no later than 120 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable. For batches with 20 or more applications, a final agency decision will be rendered by the Commissioner no later than 180 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable.

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

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

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

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

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

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

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

(b) The expedited review process involves review of a certificate of need application by the Department. It does not include a review by the State Health Planning Board. The expedited review process will include 12 review cycles. The beginning of each cycle shall be the first business day of each month and a decision the Commissioner shall render shall be rendered by the Commissioner no later than 90 days thereafter, unless otherwise specified by rule or notice.

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

Public Notice: Invitation for Certificate of Need Applications
 See: 24 N.J.R. 4426(b); 25 N.J.R. 2596(c); 25 N.J.R. 4520(b), 25 N.J.R. 4795(e).
 Amended by R.1993 d.442, effective September 7, 1993.
 See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
 Amended by R.1996 d.101, effective February 20, 1996.
 See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).
 Public Notice: Invitation for Certificate of Need Applications.
 See: 34 N.J.R. 2473(a).
 Amended by R.2002 d.243, effective August 5, 2002.
 See: 34 N.J.R. 458(a), 34 N.J.R. 2814(a).
 Rewrote the section.
 Public Notice: Invitation for Certificate of Need Applications.
 See: 34 N.J.R. 3991(b), 4226(a).
 Public Notice: Certificate of Need and Acute Care Licensure.
 See: 35 N.J.R. 277(a), 277(b).
 Public Notice: Invitation for Certificate of Need Applications.
 See: 35 N.J.R. 1739(c).
 Public Notice: Certificate of Need: Application and Review Process.
 See: 35 N.J.R. 4789(c), 5444(c).
 Public Notice: Cancellation of Certificate of Need.
 See: 36 N.J.R. 1834(a), 1835(a), 1835(c), 1836(a), 1836(b), 2263(a), 4997(a), 5460(a), 5460(b), 5460(c), 5460(d), 5461(a)
 Public Notice: Cancellation of Certificate of Need Calls
 See: 37 N.J.R. 4580(a), 4580(b).

Case Notes

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

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

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

8:33-4.3 Submission of applications

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

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

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

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

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

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

8:33-4.4 Certificate of need filing requirements

(a) An applicant shall document in the application that he or she owns the site where the facility, service, or equipment will be located, or has an ownership or lease option for such site, which option is valid at least through the certificate of need processing period. A duly executed copy of the deed, option or lease agreement for the site shall be submitted with the certificate of need application and include identification of site, terms of agreement, date

of execution and signature of all parties to the transaction. If the site is optioned or leased by the applicant, a copy of the deed held by the current owner shall be required at the time of filing.

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

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

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

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

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

8:33-4.5 Review for completeness

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

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

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

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

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, proposed operator, or change in site after the application submission deadline date. An applicant desiring to make such a modification or alteration shall be required to withdraw the application from the current cycle and submit a new application for the next cycle.

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

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

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

8:33-4.7 Deferral of applications

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

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

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

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

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

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

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

8:33-4.8 Withdrawal of applications

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

8:33-4.9 General criteria for review

(a) No certificate of need shall be issued unless the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be financially accomplished and licensed in accordance with applicable licensure regulations, will not have an adverse impact on access to health care services in the region or 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: