

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

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

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

- (1) Hospital administration and governance;
- (2) Patient services;
- (3) Quality improvement;
- (4) Patient health care needs;
- (5) Safety and infection control;
- (6) Comfort and pain management;
- (7) Skin integrity;
- (8) Psychosocial and spiritual health;
- (9) Patient and family education;
- (10) Discharge planning;
- (11) Technical aspects of care; and

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

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

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

ii. Each report shall be accompanied by supporting data.

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

i. In the event that the Commissioner shall extend the period of the demonstration project by written notice, the same standards and conditions set forth in

the initial notice of approval shall continue to apply during the duration of the extension of the demonstration project.

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

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

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

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

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

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

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

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

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

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

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

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

Amended by R.1998 d.303, effective June 15, 1998.
See: 30 N.J.R. 303(a), 30 N.J.R. 2270(b).

Inserted (a) and (b).
Amended by R.1999 d.272, effective August 16, 1999.
See: 31 N.J.R. 950(a), 31 N.J.R. 2375(a).
Added (d).

SUBCHAPTER 4. THE REVIEW PROCESS

8:33-4.1 Request for certificate of need applications

(a) The full review process involves the review of a certificate of need application by the local advisory board(s) and the State Health Planning Board, as well as the Department. The full review process for certificate of need applications shall be activated upon notice by the Commissioner inviting certificate of need applications for specific services. The notice shall become effective upon the date of publication in the New Jersey Register. The notice shall also be distributed to the local advisory boards and to health care associations on file with the Department. The Commissioner shall publish in the New Jersey Register in February of each year an anticipated schedule for receipt of certificate of need applications subject to full review procedures for a two-year period, including the current calendar year. The Commissioner may announce additional or special calls for certificate of need applications beyond those identified in the yearly notice or may delete announced calls from the yearly notice. Changes to the published schedule shall be published in the New Jersey Register. Wherever practical, the Commissioner shall provide notice in accordance with this section to allow for a minimum of 90 days between the date of publication of the Commissioner's notice inviting certificate of need applications and the date for submission of applications in response to the notice(s). The notice shall identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, the date the application is deemed complete for processing, the date the local advisory board must submit its recommendation to the Commissioner and the date that the State Health Planning Board must submit its recommendation to the Commissioner. The local advisory board(s) shall forward recommendations to the State Health Planning Board and Commissioner within 45 days after the application is deemed complete for processing and the State Health Planning Board shall forward recommendations to the Commissioner within 90 days after the application is deemed complete for processing unless a fair hearing is requested by an applicant in accordance with the procedures identified at N.J.A.C. 8:33-4.14. For batches with fewer than 20 applications, a final agency decision will be rendered by the Commissioner no later than 120 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable except where a hearing is requested as set forth in N.J.A.C. 8:33-4.10(e)4. For batches with 20 or more applications, a final agency decision will be rendered by the Commissioner no later than 180 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable except where a hearing is requested as set forth in N.J.A.C. 8:33-4.10(e)4.

(b) The direct review process involves the review of a certificate of need application by the State Health Planning Board, as well as the Department. The direct review process for certificate of need applications shall be activated upon notice by the Commissioner inviting certificate of need applications for specific services. The notice shall become effective upon publication in the New Jersey Register. The notice shall also be distributed to the local advisory boards and to health care associations on file with the Department. The Commissioner shall publish in the New Jersey Register in February of each year an anticipated schedule for receipt of certificate of need applications subject to direct review procedures for a two-year period including the current calendar year. The Commissioner may announce additional or special calls for certificate of need applications beyond those identified in the yearly notice or may delete announced calls from the yearly notice. Changes to the published schedule shall be published in the New Jersey Register. Wherever practical, the Commissioner shall provide notice in accordance with this section to allow for a minimum of 90 days between the date of publication of the Commissioner's notice inviting certificate of need applications and the date for submission of applications in response to the notice(s). The notice will identify the needed service(s), proposed geographic area(s) to be served, the date the application is due, the date the application is deemed complete for processing, and the date the State Health Planning Board must submit its recommendation to the Commissioner. The State Health Planning Board shall forward recommendations to the Commissioner within 90 days after the application is deemed complete for processing unless a fair hearing is requested by an applicant in accordance with the procedures identified at N.J.A.C. 8:33-4.14. For batches with fewer than 20 applications, a final agency decision should be rendered by the Commissioner no later than 120 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable, except where a hearing is requested as set forth in N.J.A.C. 8:33-4.10(e)4. For batches with 20 or more applications, a final agency decision should be rendered by the Commissioner no later than 180 days after receipt of recommendations from the State Health Planning Board or a decision from the Office of Administrative Law, as applicable, except where a hearing is requested as set forth in N.J.A.C. 8:33-4.10(e)4.

(c) The expedited review process involves review of a certificate of need application by the Department. It does not include a review by the local advisory board(s) or State Health Planning Board. The expedited review process will include 12 review cycles. The beginning of each cycle shall be the first business day of each month and a decision shall be rendered by the Commissioner no later than 90 days thereafter except where a hearing is requested as set forth in N.J.A.C. 8:33-4.10(e)4.

(d) The Department shall conduct an annual review of the certificate of need application and review process to

determine timeliness in processing certificate of need applications. Failure by the Department to process at least 90 percent of certificate of need applications filed within the year within the timeframes stated herein shall result in immediate corrective action.

Public Notice: Invitation for Certificate of Need Applications
 See: 24 N.J.R. 4426(b); 25 N.J.R. 2596(c); 25 N.J.R. 4520(b), 25 N.J.R. 4795(e).
 Amended by R.1993 d.442, effective September 7, 1993.
 See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a).
 Amended by R.1996 d.101, effective February 20, 1996.
 See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a).

Case Notes

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

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

8:33-4.2 Development of applications

(a) Application for a certificate of need shall be made to the Department, in accordance with the requirements of this chapter, and shall be in such form and contain such information as the Department may prescribe.

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

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

8:33-4.3 Submission of applications

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

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

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

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

<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. Hospital-based subacute care units:	\$5,000
3. Change in scope of financing:	\$5,000
4. Change in cost:	\$5,000 + 0.15% of new TPC— initial fee
5. Extension of time	\$5,000
6. Transfer of ownership	\$5,000

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

8:33-4.4 Certificate of need filing requirements

(a) An applicant shall document in the application that he or she owns the site where the facility, service, or equipment will be located, or has an ownership or lease option for such site, which option is valid at least through the certificate of need processing period. A duly executed copy of the deed, option or lease agreement for the site shall be submitted with the certificate of need application and include identification of site, terms of agreement, date of execution and signature of all parties to the transaction. If the site is optioned or leased by the applicant, a copy of the deed held by the current owner shall be required at the time of filing.

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

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

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

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

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

8:33-4.5 Review for completeness

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

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