

2. If an applicant requires an extension of time beyond the expiration date of the certificate of need, an application for extension of time shall be filed 60 days prior to the current expiration date. The application shall be subject to the expedited review process at N.J.A.C. 8:33-5.1. The application shall not be deemed complete unless the applicant provides documentation that the project's financing remains in place and is sufficient to cover cost increases, and that local zoning and/or local building approvals have already been obtained. The application shall document the reasons for delays and proposed detailed time frame identifying the remaining time needed for the project to be approved and/or licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable. Where the Commissioner determines that the approval should be extended for an additional time beyond its current expiration date, he or she shall assign an expiration date, based on the criteria contained in (a)3 below. Where the Commissioner denies the request for extension, the applicant may request a hearing pursuant to the Administrative Procedure Act, P.L. 1968, c.410 (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, in accordance with N.J.S.A. 26:2H-9. Requests for a hearing shall be made to the Department within 30 days of receipt of notification of the Commissioner's action. The Department shall arrange for a hearing within 60 days of receipt of a request, and after such hearing the Commissioner or his or her designee shall furnish the applicant with the hearing examiner's written recommendations and reasons therefor. The Commissioner, within 30 days of receiving all appropriate hearing records, shall make his or her determination, which shall be a final agency decision.

3. If the project has not been licensed by the Department's Certificate of Need and Acute Care Licensure Program or Long Term Care Licensing and Certification Program, as applicable, within the original or, if applicable, extended time frame identified within this subchapter, the certificate of need shall automatically be deemed to be terminated.

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).
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.

8:33-3.11 Demonstration and research projects

(a) Projects which satisfy the definition of a research project, as specified at N.J.A.C. 8:33-1.3, shall be exempt from certificate of need requirements as long as they are conducted exclusively for the purposes of investigational studies and scientific research.

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

(c) This subsection sets forth the requirements for an inner city cardiac satellite demonstration project:

1. The purpose of an inner city cardiac satellite demonstration project, as defined in N.J.A.C. 8:33-1.3, is to test the hypothesis that permitting a licensed inner city teaching hospital to provide invasive therapeutic cardiac services at a satellite hospital within the same hospital system shall maintain or improve the financial stability of the inner city hospital and promote the continued provision of the full range of services and programs which it provides. This project allows qualifying hospital systems to generate greater revenue for inner city hospitals by enabling them to provide invasive therapeutic cardiac services at a satellite hospital, the benefits of which shall then be credited to the inner city hospital, thereby enabling the inner city hospital to improve access to and the quality of invasive therapeutic cardiac services to medically underserved populations.

2. Inner city cardiac satellite demonstration projects shall obtain a CN pursuant to the expedited review process set forth in N.J.A.C. 8:33-5 and in response to a call issued by the Department. All activities of both the inner city hospital and the satellite hospital shall be governed by the rules concerning cardiac surgery centers, at N.J.A.C. 8:33E.

3. In order to implement the demonstration project gradually, the Department shall accept no more than two certificate of need applications, for cardiac satellite demonstration projects in any consecutive 24-month period, beginning on July 1, 1998. In addition to meeting the remaining criteria set forth in this subsection, only those applicants providing convincing evidence that the proposed project shall increase access to invasive therapeutic cardiac services among minority and medically underserved populations through the increased revenue reasonably expected through implementation of the project, shall be accepted.

4. An inner city cardiac satellite demonstration project shall submit an application to the Department that, at a minimum, demonstrates that the proposed inner city cardiac satellite demonstration project satisfies the following criteria:

i. The inner city hospital shall be part of a multi hospital system and shall be a licensed teaching hospital

that provides a comprehensive complement of invasive therapeutic cardiac services;

ii. Prior to the provision of the invasive therapeutic cardiac services at the satellite hospital, and on a periodic basis thereafter as determined by the Department, the inner city hospital and the satellite hospital shall each comply with all licensure criteria governing the provision of invasive therapeutic cardiac services, including those contained within N.J.A.C. 8:43G-7;

iii. Net revenues generated from the provision of invasive therapeutic cardiac services at the satellite hospital shall be utilized to benefit the inner city hospital. Upon application, the inner city hospital shall provide to the Department a report prepared by an independent accounting firm approved by the Department. The report shall provide an estimated projection of the amount of net revenues and expenses expected as a result of the implementation of an inner city cardiac satellite demonstration project, together with the methodology utilized to calculate the reported net revenues. The methodology shall comport with fair market valuation of all costs and revenues. The report shall further set forth a plan demonstrating the manner in which reported net revenues shall be used to increase access to and the quality of invasive therapeutic cardiac services at the inner city hospital and to promote, generally, the financial stability of the inner city hospital and the continued provision of the full range of services and programs which it provides. Upon the conclusion of the first calendar year of operation of the inner city cardiac satellite demonstration project, and each year of operation thereafter, the inner city hospital shall provide to the Department an accounting, in a standardized format to be determined by the Department, containing the net revenues that have been utilized to benefit the inner city hospitals. In addition, a complete financial report from the satellite hospital shall be submitted to the Department, including all expenses and other financial information related to the invasive therapeutic cardiac center, and the services it provides. This report shall be submitted to the Department within 60 days after the close of each calendar year;

iv. The provision of invasive therapeutic cardiac services at a satellite hospital in accordance with this subsection shall not result in a diminution of the volume or quality of services at the inner city hospital, as compared to the volume and quality of services prior to the initiation of the demonstration project. Volume shall not decrease 20 percent or more below the previous level, and the quality shall not decrease, as measured by risk-adjusted mortality rates, compliance with nationally recognized quality improvement initiatives and other measures as determined by the Department on a case-by-case basis, depending upon the facts and circumstances. Upon application, the inner city hospital shall submit a plan that demonstrates how the volume and quality of the invasive therapeutic cardiac services at the inner city hospital will be maintained. Notwithstanding the foregoing, the inner city hospital shall satisfy the regulatory requirements set forth at N.J.A.C. 8:33E-2.3 that are applicable to invasive therapeutic cardiac procedures, governing volume and quality of services. If the Department determines that the volume at the inner city hospital has decreased by 20 percent or more, or the quality is lower to a degree, for a consecutive 12-month period, the Department shall have the authority to rescind the satellite hospital's license to operate its invasive therapeutic cardiac services, upon notice to the inner city hospital and a six-month period to cure the deficiencies. The Department's determination to rescind the inner city hospital's license hereunder shall be final;

v. The provision of invasive therapeutic cardiac services at the satellite hospital shall be subject to the governance of the inner city hospital and operated in accordance with the policies, procedures, and protocols of the inner city hospital which shall hold the license;

vi. Every inner city cardiac satellite demonstration project shall record and maintain data on the operation of the project, the patients served, the outreach to minority and indigent communities, and other information requested of each project by the Department. Such data shall be reported in a standardized format determined by the Department, and provided to the Department on a quarterly basis within 30 days after the close of each quarter;

vii. The inner city hospital shall ensure the provision of invasive therapeutic cardiac services at both the satellite hospital and the inner city hospital and shall assure that both hospitals comply and continue to comply with all applicable licensure rules.

5. All facilities seeking to initiate an inner city cardiac satellite demonstration project pursuant to an approved certificate of need issued in accordance with the demonstration criteria described in this subchapter shall be initially licensed on an annual basis, in accordance with the provisions of N.J.A.C. 8:43G.

6. Licenses for inner city cardiac satellite demonstration project facilities may be renewed on an annual basis only upon a 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. 8:43B; N.J.A.C. 8:33; 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.

7. These requirements for licensure shall be in addition to and not in limitation of any other applicable authorities not specifically mentioned herein and from which the facility in question has not been specifically exempted by law.

(d) The Commissioner shall accept certificate of need applications for bloodless surgery demonstration projects in accordance with the provisions of the expedited review process set forth at N.J.A.C. 8:33-5.1(a) following a call for applications.

1. The Commissioner shall approve, in writing, no more than two certificate of need applications for bloodless surgery demonstration projects in any consecutive 24-month period, beginning on August 16, 1999.

2. The Commissioner shall approve each bloodless surgical demonstration project for a period of no more than 30 months from the date of notice of the written approval, but the Commissioner, in his or her discretion, may extend the date of termination of a demonstration project upon written request made by the hospital approved for the bloodless surgical demonstration project, and the extent that the utilization, staffing, outcome, policy and procedure criteria of this rule have been achieved during the course of the demonstration period.

3. An applicant for a bloodless surgery demonstration project shall:

i. Be a general hospital meeting the requirements set forth at N.J.A.C. 8:33E and 8:43G; and

ii. Have an existing invasive cardiac diagnostic service that has been in compliance with the minimum annual utilization requirements at N.J.A.C. 8:33E-1.4(b)1 and the cardiac licensing requirements at N.J.A.C. 8:43G-7 for at least the three year period prior to the date of submission of the application for the bloodless surgery demonstration project.

4. A general hospital proposing to engage in a bloodless surgery demonstration project shall submit an application to the Department demonstrating the following:

i. That the applicant's bloodless surgery demonstration program shall serve a minimum of 100 patients per year in which each procedure, if performed conventionally, would result in a blood loss of greater than or equal to 1,000 cubic centimeters;

ii. That the applicant shall have qualified staff and staffing levels for the bloodless surgery demonstration project at all times that shall promote safety, including a bloodless surgery program coordinator who shall be a graduate of an accredited school of nursing and hold a current license to practice nursing care in New Jersey, and who shall be responsible for administration of:

- (1) Patient care activities;
- (2) Compilation of statistical information;
- (3) Marketing activities designed to promote patient access;
- (4) Physician referrals;
- (5) Program staffing;
- (6) Maintenance of policies and procedures; and
- (7) Consultation services;

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. A general 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, 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 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.

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).

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 Department to examine the relationship of the proposed project to the applicable plans, guidelines, and criteria.