

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).

Amended by R.2007 d.387, effective December 17, 2007.

See: 39 N.J.R. 3462(a), 39 N.J.R. 5316(b).

Added new (e); and recodified former (e) as (f).

Case Notes

Although N.J.A.C. 8:33-3.11(e) authorized a call made by the Commissioner of the Department of Health and Senior Services that invited health care facilities without a cardiac surgery facility on site to apply for a certificate of need to conduct elective angioplasty, the regulation, as applied, violated fundamental principles relating to the regulatory process; as a result, certificates of need granted for demonstration projects were not sustainable and the projects were directed to continue only through November 30, 2007, and the Commissioner was directed to promulgate proper regulations, after appropriate adherence to the principles of rulemaking, before any such demonstration project could be continued. *Cooper Univ. Hosp. v. Jacobs*, 191 N.J. 125, 922 A.2d 731, 2007 N.J. LEXIS 600 (2007).

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).

Public Notice: Invitation for Certificate of Need Applications.

See: 38 N.J.R. 1474(a), 1773(a).

Public Notice: Cancellation of Certificate of Need Calls.

See: 38 N.J.R. 5416(a).

Public Notice: Cancellation of Certificate of Need Calls.

See: 39 N.J.R. 802(a), 802(b), 802(c), 802(d), 803(a), 803(b), 803(c), 803(d), 804(a), 804(b).

Public Notice: Cancellation of Certificate of Need Calls.

See: 40 N.J.R. 6867(b).

Public Notice: Postponement of Certificate of Need Calls.

See: 40 N.J.R. 6868(a).

Case Notes

N.J.A.C. 8:33-4.1, with its regularized schedule allowing providers to submit certificate of need applications for maternal and child health needs, provided ample basis for the determination by the Commissioner of the New Jersey Department of Health and Senior Services to accept and process a hospital's application seeking a change in classification to a regional perinatal center, even though the published call notice did not include an explicit reference to a "change in designation." In re Virtua-West Jersey Hosp. Voorhees, 194 N.J. 413, 945 A.2d 692, 2008 N.J. LEXIS 410 (2008).

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.