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 shall accept certificate of need applications from general hospitals for participation in the elective angioplasty demonstration project, in accordance with the full review process at N.J.A.C. 8:33-4.1 following a call for applications.

1. The purpose of the State's participation in the Atlantic C-PORT-E trial through the approval of certificates of need to participate in the elective angioplasty demonstration project is to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty or PCI with and without on-site CABG surgical back-up.

2. The Commissioner shall approve, in writing, no more than 12 certificate of need applications for participation in the elective angioplasty demonstration project.

3. Notwithstanding the duration of demonstration projects set forth at (f)4 below, the Commissioner shall issue certificates of need to participate in the elective angioplasty demonstration project for a period that extends for nine months following the publication of the trial results in a peer-reviewed journal, which certificates of need are annually renewable during the period, and provided that such certificates of need shall be valid only during the period that cases are being entered in the Atlantic C-PORT-E registry.

i. The Department may extend the certificates of need to participate in the elective angioplasty demonstration project on an annual basis only if the Medical Director of the Atlantic C-PORT-E registry submits written notice to the Commissioner that the Atlantic C-PORT-E registry is authorized to continue patient entry in the registry.

ii. Absent a valid certificate of need, participating hospitals in the Atlantic C-PORT-E registry shall discontinue patient enrollment and cease performance of elective angioplasty or PCI. Certificate holders are allowed to comply with final reporting and other administrative requirements associated with participation in the Atlantic C-PORT-E registry.

iii. Prior to licensure by the Department to continue elective PCI in the Atlantic C-PORT-E registry, all elective angioplasty demonstration project hospitals shall provide written attestation to the Department that it will comply with all protocols and standards set forth in the Atlantic C-PORT-E registry Manual of Operations and Department PCI licensing standards, including, but not limited to:

(1) Agreement to abide by physician, patient and device selection criteria;

(2) Approval of the registry protocol by the demonstration project's Institutional Review Board;

(3) Agreement to comply with Atlantic C-PORT-E minimum annual facility and physician PCI volume requirements and Department annual PCI volume and licensing requirements set forth at N.J.A.C. 8:33E and 8:43G-7;

(4) Agreement to perform elective PCI only via the Atlantic C-PORT-E registry protocol and only while cases are being entered in the registry;

(5) Agreement to collect and transmit Atlantic C-PORT-E trial nine-month follow-up data and Atlantic C-PORT-E registry data in a timely fashion;

(6) Agreement to maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review;

(7) Agreement that the demonstration project hospital is willing to report elective PCI data to the Department separate from data collected as part of the registry protocol, to support the Department's ongoing monitoring of licensed cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10; and

(8) Agreement to obtain necessary informed consent for patient participation in the demonstration.

4. A licensed general hospital is eligible to submit applications for certificates of need to participate in the elective angioplasty demonstration project if the applicant hospital is not currently licensed to perform cardiac surgery; has signed one or more agreements with one or more New Jersey-licensed cardiac surgery centers indicating that the New Jersey-licensed cardiac surgery center is willing to participate in the Atlantic C-PORT-E trial, including collecting and submitting data to the principal investigator, as the center with on-site surgery to which some of the appli-

cant hospital's patients will be randomly assigned for elective PCI; and the applicant hospital:

i. Is licensed to provide primary PCI; or

ii. Has an approved but not yet implemented certificate of need to provide primary PCI services.

5. The Department's issuance of a certificate of need to a participating hospital pursuant to this subsection is conditioned upon the following:

i. A participating hospital shall provide elective angioplasty or PCI only on patients enrolled or entered in the Atlantic C-PORT-E trial or registry.

ii. A participating hospital that discontinues its participation in the Atlantic C-PORT-E trial or registry, whether voluntarily or involuntarily, shall immediately cease performing elective angioplasty or PCI, shall notify the Department of the termination of its participation in the Atlantic C-PORT-E trial or registry and shall return the certificate of need authorizing it to participate in the elective angioplasty demonstration project to the Department within 30 days of the date that its participation ceases, and the Department shall issue the hospital an amended certificate of need deleting its authorization to participate in the elective angioplasty demonstration project.

iii. When the Atlantic C-PORT-E trial publishes the trial results in a peer-reviewed journal, all hospitals participating in the elective angioplasty demonstration project shall cease performing elective angioplasty or PCI, and shall return the certificates of need authorizing them to participate in the elective angioplasty demonstration project to the Department within nine months of the date of publication of the trial results, and the Department shall issue amended certificates of need and licenses to the participating hospitals deleting their authorization to participate in the elective angioplasty demonstration project.

iv. Should all Atlantic C-PORT-E trial enrollment conclude abruptly as a result of application of the trial's stopping rules (that is, generally, because the early evidence convincingly indicates safety problems), the State's participation in the trial shall terminate, and all participating hospitals shall immediately cease performing elective angioplasty or PCI and shall return their certificate of need to the Department within 30 days of the date that enrollment ceases, and the Department shall issue each hospital an amended certificate of need deleting its authorization to participate in the elective angioplasty demonstration project.

v. All participating hospitals shall continue to provide required documentation as required in the protocol Atlantic C-PORT-E trial and registry.

6. Applicants shall submit documentation addressing the following:

i. How the applicant will satisfy the study site inclusion criteria specified in the protocol for Atlantic C-PORT-E trial including:

(1) Capability of performing a specified minimum volume of diagnostic cardiac catheterizations per year;

(2) Agreement to complete an elective PCI development program;

(3) Agreement to abide by physician, patient and device selection criteria defined in "The Atlantic C-PORT Trial, Elective Angioplasty Study, Manual of Operations," Version 3.0 (March 24, 2006), (Manual of Operations), as amended and supplemented;

(4) Agreement to collect and transmit study data in a timely fashion;

(5) Agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study; and

(6) Agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review;

ii. The agreement of the applicant's proposed participating interventional cardiologist to satisfy the following participating interventional cardiologist inclusion criteria:

(1) That the cardiologist meets and will continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6;

(2) That the cardiologist agrees to practice in accordance with the Atlantic C-PORT-E trial defined device and patient selection criteria; and

(3) That the cardiologist agrees to obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients;

iii. How the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which are designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations;

iv. The approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application;

v. How the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 PCI cases in year two and each year thereafter);

vi. The applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, and compliance with N.J.A.C. 8:33E-2.16(b) and 8:43G-7 as applicable;

vii. The applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of licensed cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10; and

viii. The status of the applicant's application to participate in the elective angioplasty demonstration project, upon which acceptance issuance of a certificate of need is contingent, and proof of which acceptance the applicant shall submit to the Department.

7. The Department shall approve up to 12 applications for certificates of need to participate in the elective angioplasty demonstration project, after consideration of the documentation submitted pursuant to (e)6 above, the criteria at N.J.S.A. 26:2H-8 and the following criteria:

i. The applicant's ability to offer a high quality program;

ii. The applicant's ability to provide patient selection from among a community that is representative of the State's diverse regions and urban, suburban, and/or rural populations;

iii. The potential to increase access to care for minorities and the medically underserved by selection of the applicant; and

iv. The projected demonstration project elective PCI case volume by selection of the applicant.

(f) 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).
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).
Amended by R.2011 d.199, effective August 1, 2011.
See: 43 N.J.R. 801(a), 43 N.J.R. 1866(b).

In the introductory paragraph of (e)3, and in (e)3i and (e)3ii, substituted "registry" for "trial" following "C-PORT-E" throughout; in the introductory paragraph of (e)3, substituted "that extends for nine months following the publication of the trial results in a peer-reviewed journal" for "of no more than three years, not counting any intervening lapse in enrollment associated with the pendency of litigation described at *Cooper University Hospital v. Jacobs*, 191 *N.J.* 125 (2007)" and "entered" for "enrolled", and deleted "three-year" preceding the second occurrence of "period,"; in (e)3i, substituted "entry in the registry" for "enrollment"; added (e)3iii; in (e)5i, inserted "or entered" and "or registry"; in (e)5ii, inserted "or registry" twice; rewrote (e)5iii; and in (e)5v, inserted "and registry".

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:

Category	Deadline for Submission
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.