submission with the Department in response to any submitted certificate of need applications that have been deemed complete. The published call shall set forth timeframes for the submission of applications, the opportunity for affected facilities to obtain copies of the applications, and the written submissions by affected facilities responding to the applications.

i. A written submission filed by an affected facility may address the anticipated impact on quality of care of the proposed new program on the affected facility, in accordance with the provisions of N.J.S.A. 26:2H-8, and may also document the impact of technological and/or medical advances on the future need for cardiac surgery services in the petitioner's county and contiguous counties.

ii. The State Health Planning Board shall consider the issues addressed in the submissions of existing New Jersey cardiac surgery centers in making its recommendation to the Commissioner. The State Health Planning Board shall also afford affected facilities and applicants the opportunity to address the impact of the application(s) on quality of care as well as the impact of technological and/or medical advances on the future need for cardiac surgery services in its open public meeting.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote the section.
Recodified from N.J.A.C. 8:33E-2.15 and amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote (a). Former N.J.A.C. 8:33E-2.14, Compliance, recodified to N.J.A.C. 8:33E-2.13.
Repeal and new rule, R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Section was "Submission of Certificate of Need applications".
Public Notice: Cardiac surgery petition criteria.
See: 34 N.J.R. 1554(a).
Petition for Rulemaking.
See: 34 N.J.R. 3030(a).
Public Notice: Cardiac surgery center certificate of need applications.
See: 34 N.J.R. 3135(b), 3136(a).
Petition for Rulemaking.
See: 35 N.J.R. 476(a).
Public Notice: Cardiac Diagnostic Facilities and Cardiac Surgery Centers.
See: 35 N.J.R. 1739(b).
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In (a), rewrote 1i, and substituted "(a)1 above" for "(a)1i above" and rewrote the last sentence in the introductory paragraph of 4.
Public Notice: Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, Cardiac Surgery Petition Criteria.
See: 36 N.J.R. 1835(b).
Public Notice: Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, Cardiac Surgery Petition Criteria.
See: 37 N.J.R. 1892(a).

8:33E-2.15 Competitive review criteria

(a) The Department's goal in considering applications for additional cardiac surgery programs is to improve access to all cardiac services, especially for medically underserved and minority populations, while at the same time ensuring the quality of services at cardiac surgery centers. The Department also seeks to foster collaboration among existing healthcare providers offering preventive, primary, diagnostic and therapeutic cardiac services when considering applications for additional invasive therapeutic cardiac services programs.

(b) During certificate of need review, consideration for approval shall be limited to the applicant(s) that meets the following requirements and does so to a greater extent than the competing applicants, has documented compliance with the following competitive review criteria and has documented compliance with all other applicable criteria in this subchapter and N.J.S.A. 26:2H-8. Unless otherwise specified in the certificate of need call issued by the Commissioner, a maximum of one new cardiac surgery program shall be considered for approval in any certificate of need call under these competitive review criteria.

1. The applicant is able to provide quantifiable documentation of its historic commitment to access to cardiac services, including preventive and primary cardiac services as well as invasive cardiac diagnostic services, for minority and medically underserved populations;

i. The applicant shall provide documentation, which shows the proportion of minority and medically underserved residents residing in the proposed service area, which shall be no larger than the county in which the applicant is located as well as contiguous counties;

ii. The applicant is able to provide a plan that is designed to ensure that appropriate access to the preventive, primary, diagnostic, and therapeutic cardiac interventions by minority and medically underserved populations, and other population groups that have historically been underrepresented in the provision of cardiac surgical services (for example, Medicaid recipients, indigent/self-pay patients), shall be achieved. The plan is subject to review and approval by the Department. The Department's approval shall be based on the hospital's demonstration that, to the maximum extent possible, it will provide cardiac therapeutic interventions to minority and medically underserved populations in comparable proportion to the general population in the hospital's proposed service area. This plan may serve as a basis for conditions placed on certificate of need approval;

2. The applicant is able to document that it has collaborated over at least the previous two years with either existing in-State cardiac surgery centers located within the applicant's county, unless the applicant demonstrates compelling reasons consistent with good patient care to be collaborating with a cardiac surgery center(s) in a contiguous county, or where there is no existing cardiac surgery center located within the county, then with one of the two closest cardiac surgery centers. Except in cases where the applicant can demonstrate that the closest in-State cardiac surgery center is geographically remote from

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applicant and would present an access problem for patients, such collaboration shall minimally include documentation that the applicant's transfer agreements with existing in-State cardiac surgery centers are in use. Applicants able to document participation in a comprehensive system of collaboration with an existing in-State cardiac surgery center, including such elements as joint credentialing of physicians, planning, training, transportation arrangements, development of care paths, and case review, technological linkages, etc., resulting in an integrated continuum of cardiac care for patients, are preferred;

3. The applicant is able to provide quantifiable documentation that, despite its collaborative efforts, there exist geographic access problems for invasive therapeutic cardiac services that include, but are not limited to, factors such as distance, in terms of mileage or average travel time, to alternate cardiac surgery centers within its county or contiguous counties. Documentation of minority and/or elderly residents in the applicant's proposed service area shall be considered in evaluating the applicant's documentation of geographic access problems;

4. The applicant is able to provide the Department with independently audited data on major complication rates, including mortality, myocardial infarctions, sustained ventricular arrhythmia, neurological complications and major vascular complications, which together comprise no more than two percent of all diagnostic cardiac catheterizations performed in the applicant's facility during the most recent three years;

5. The applicant is able to provide quantifiable documentation that the initiation of its new service shall not have an adverse impact on the quality of care or the efficient delivery of health care services in the region or Statewide in accordance with N.J.S.A. 26:2H-8;

6. The applicant is able to provide quantifiable documentation of its ability to capture cases that are currently being performed at out-of-State cardiac surgery centers;

7. The applicant can demonstrate that there is availability of sufficient manpower in the several professional disciplines (for example, physicians, nurses, physician assistants, and perfusion therapists) that will be used to staff the new or additional cardiac surgical services; and

8. The applicant may document the impact of technological and/or medical advances on the future need for cardiac surgery services in the applicant's county and contiguous counties.

New Rule, R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Recodified from N.J.A.C. 8:33E-2.16 and amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Former N.J.A.C. 8:33E-2.15, Submission of Certificate of Need applications, recodified to N.J.A.C. 8:33E-2.14.
Repeal and new rule, R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Section was "Competitive review criteria".
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).

8:33E-2.16 Submission of certificate of need applications for the provision of PCI in emergent situations with off-site cardiac surgery back-up

(a) The Department's goal in considering applications for provision of PCI without the availability of on-site cardiac surgery in emergent situations is to promote wider access to appropriate emergency PCI services while assuring quality of care to patients with acute myocardial infarction. Certificate of need applications shall be accepted on the first business day of each month and shall follow the expedited review process.

1. Any general hospital having a full service adult diagnostic cardiac catheterization program that has been licensed for at least six months as a full service adult diagnostic cardiac catheterization program prior to the application submission date may apply provided it has documented, to the satisfaction of the Department, licensure and full compliance with all cardiac catheterization program and facility utilization requirements as set forth in this chapter and N.J.A.C. 8:43G-7 for the most recent four quarters of operation fully documented by the Department.

(b) The criteria in (b)1 through 11 below shall be considered by the Commissioner in determining whether to grant a certificate of need. The Commissioner may also consider additional information provided by an applicant that the Commissioner deems relevant to such determination.

1. The applicant is able to document collaboration with a New Jersey cardiac surgery center located in the same municipality as the applicant, or, if there is none in the same municipality, with a New Jersey cardiac surgery center located in the same county or a contiguous county. The documented collaboration must include at a minimum:

i. Written protocols assuring that patients will be transferred to and received at the cardiac surgery center's operating room within one hour from time of the determination by the primary operator of the need for transfer. Protocols shall include provisions for emergency transport of patients requiring an intra-aortic balloon pump (IABP);

ii. Regular consultation on individual cases, including use of technology to share case information in a rapid manner; and

iii. Evidence of adequate cardiac surgery on-call back up;

2. The applicant is able to document how case selection for primary PCI will comply rigorously with the criteria identified in (c) below;

3. The applicant is able to document how the general public will be advised of the availability of primary PCI with off-site surgical back-up, and of the protocols for transfer; as well as how informed consent will be secured from patients;

4. The applicant is able to document, based on acute myocardial infarction (AMI) cases admitted in the previous two years in which thrombolytic therapy was administered or the patient was transferred to a cardiac surgery center for primary angioplasty, that it will in its second year of operation perform a minimum of 36 primary PCI cases per year. The applicant is able to document that it will maintain this minimum volume in subsequent years. Primary PCI intervention must be performed routinely as the treatment of choice for a large proportion of AMI patients to ensure adequate facility volume. Detailed policies to ensure effective care paths must be developed;

5. The applicant is able to document that primary PCI will be available 24 hours/day, seven days per week;

6. The applicant is able to document that each operator performing primary PCI is an experienced interventionalist who performed at least 75 PCI cases at a cardiac surgery center in the previous year and continues to do so during his or her tenure at the free-standing PCI site;

7. The applicant is able to document that its technical catheterization laboratory staff have been trained at an interventional laboratory in a cardiac surgery center;

8. The applicant is able to document that the catheterization laboratory will be equipped with resuscitative equipment, an intra-aortic balloon pump (IABP) support, and a broad array of interventional equipment, as well as meeting all equipment standards at N.J.A.C. 8:43G-7.19;

9. The applicant is able to document its ability to recruit a laboratory medical director board-certified in interventional cardiology by the Cardiovascular Subspecialty Board of the American Board of Internal Medicine, as well as a sufficient number of cardiac care unit nurses with training and experience in hemodynamic monitoring and IABP management. Physicians and support staff performing PCI services at the facility shall meet the minimum requirements for the performance of PCI procedures as set forth at N.J.A.C. 8:33E-2.4(e) and 8:43G-7.29 and 7.30;

10. The applicant is able to document its ability to perform primary PCI in a timely fashion, that is, balloon inflation no later than 120 minutes after admission; and

11. The applicant is able to document its ability to conduct a ongoing program of outcomes analysis and formalized periodic case review, as part of a broader quality assessment and error management system.

(c) The provision of primary PCI without the availability of on-site cardiac surgery shall be limited to patients with acute myocardial infarction (AMI) who present within 12 hours of onset of AMI and who demonstrate hypotension, congestive heart failure, frank cardiogenic shock, or ischemic symptoms (with ST-segment elevations compatible with AMI or an ECG that prevents diagnosis of an AMI) and these symptoms and ECG changes do not resolve with nitroglycerin. Intervention at facilities with off-site surgical back-up should be avoided in hemodynamically stable patients with:

1. Sixty percent or greater stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter;

2. Extremely long or angulated infarct-related lesions with TIMI grade 3 flow;

3. Infarct-related lesions with TIMI grade 3 flow in stable patients with three-vessel disease;

4. Infarct-related lesions of small or secondary vessels; or

5. Lesions in other than the infarct artery.

(d) In order to facilitate the Department's review of the safety and effectiveness of facilities offering primary PCI services, the Department will:

1. Consistent with N.J.A.C. 8:33E-2.10, develop quarterly reporting requirements for facilities performing primary PCI without on-site surgical back-up; and

2. Communicate guidelines concerning the circumstances under which a licensed cardiac surgery center shall assume reporting responsibility for the outcomes of patients transferred from a facility performing primary PCI without on-site surgical back-up.

(e) Facilities granted a certificate of need to provide primary PCI in emergent situations without on-site cardiac surgery are required to operate in accordance with the provisions of N.J.A.C. 8:33E-2.3(d) as applicable and (b) above, and/or any conditions imposed on its certificate of need as a condition of continued licensure. Compliance with minimum annual facility volume requirements shall be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Compliance with annual physician volume standards shall be calculated on a calendar year basis. Facilities unable to comply with the requirements of this section will be required to submit to the following:

1. An external review from an independent external organization approved by the Department to assess the overall performance of the facility and its staff; and

2. A detailed plan of correction shall be submitted to the Department within 30 days of notification of its failure

to maintain compliance with one or more of the criteria at (b) above, indicating the licensure renewal criteria that have not been achieved, the corrective actions that are to be put in place or the systemic changes that will be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers to licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction will not be considered final until it has been approved by the Department.

i. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables will result in a revocation of the facility's license unless an appeal is filed with the Commissioner within 60 days after receiving the Department's notice of revocation. The Department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it will be held in accordance with 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. At the Commissioner's discretion, the hearing will be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat;

(2) The frequency of the occurrence;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.

New Rule, R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Former N.J.A.C. 8:33E-2.16, Competitive review criteria, recodified to N.J.A.C. 8:33E-2.15.
Repeal and new rule, R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Section was "Limited PTCA trial programs".
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
Rewrote (a)1.
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
Section was "Submission of certificate of need applications for the provision of PTCA in emergent situations with off-site cardiac surgery back-up". Substituted "PCI" for "PTCA" throughout; and in introductory paragraph of (b), inserted "below".