CHAPTER 33E

CERTIFICATE OF NEED: CARDIAC DIAGNOSTIC FACILITIES AND CARDIAC SURGERY CENTERS

Authority

N.J.S.A. 26:2H–5 and 26:2H–8.

Source and Effective Date

R.2001 d.58, effective January 18, 2001.
See: 32 N.J.R. 3890(a), 33 N.J.R. 653(a).

Executive Order No.66(1978) Expiration Date

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, expires on January 18, 2006.

Chapter Historical Note

Chapter 33E, Certificate of Need: Cardiac Facilities, was originally codified in Title 8 as Chapter 41, Certificate of Need: Cardiac Facilities.

Chapter 41, Certificate of Need: Cardiac Facilities, was adopted as R.1977 d.179 and d.180. See: 9 N.J.R. 171(a), 9 N.J.R. 171(b), 9 N.J.R. 268(c), 9 N.J.R. 268(d).

Chapter 41, Certificate of Need: Cardiac Facilities, was recodified as N.J.A.C. 8:33E effective September 13, 1979.

Pursuant to Executive Order No. 66(1978), Chapter 33E, Certificate of Need: Cardiac Facilities, was readopted as R.1987 d.296, effective June 23, 1987. See: 19 N.J.R. 606(a), 19 N.J.R. 610(a), 19 N.J.R. 1304(a), 19 N.J.R. 1307(a).

Pursuant to Executive Order No. 66(1978), Chapter 33E, Certificate of Need: Cardiac Facilities, expired on June 23, 1992.

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, was adopted as R.1993 d.670, effective December 20, 1993. See: 25 N.J.R. 3712(a), 25 N.J.R. 6019(b).

Pursuant to Executive Order No. 66(1978), Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, expired on December 20, 1995.

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, was adopted as new rules by R.1996 d.104, effective February 20, 1996. See: 27 N.J.R. 3895(b), 28 N.J.R. 1252(a).

Pursuant to Executive Order No. 66(1978), Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, was readopted as R.2001 d.58, effective January 18, 2001. See: Source and Effective Date.

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SUBCHAPTER 1. CARDIAC DIAGNOSTIC FACILITIES

8:33E–1.1 Scope and purpose

(a) The purpose of this subchapter is to establish standards and general criteria for the planning of cardiac diagnostic facilities and for the preparation of an application for a certificate of need for such a facility. The invasive cardiac diagnostic facility specializes in the detection and diagnosis of cardiac disorders. Unlike the cardiac surgery center in which both diagnostic and therapeutic services are co-located, the invasive cardiac diagnostic facility does not provide cardiac surgery or PTCA but rather on the basis of diagnostic studies refers patients, where appropriate, to facilities offering cardiac surgery and other advanced cardiac diagnostic and treatment modalities. To increase access to these services N.J.A.C. 8:33E–1.12 establishes low risk cardiac catheterization programs that are subject to facility performance standards contained at N.J.A.C. 8:33E–1.4(c), 1.12(c), and 1.14 intended to ensure the continual delivery of safe, patient care, efficiently and effectively provided.

1. As of February 20, 1996, a new category of invasive cardiac diagnostic catheterization facility was established to treat only low risk adult patients. Defined at N.J.A.C. 8:33E–1.2, these facilities may apply for a certificate of

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need in response to a call under criteria as set forth at N.J.A.C. 8:33E–1.12.

(b) In the invasive cardiac diagnostic facility, the primary diagnostic services are provided by cardiac catheterization, coronary angiographic and non-invasive laboratories. The cardiac catheterization and coronary angiographic laboratories are devoted to achieving optimal quality physiological and angiographic studies. Non-invasive cardiac diagnostic services are commonly available at all acute care hospitals and may include, at a minimum, ECG instruments, exercise stress testing, Doppler technology/echocardiography equipment and Holter type monitoring and nuclear cardiology facilities.

(c) The American College of Cardiology/American Heart Association Task Force on Cardiac catheterization supports the position that the safety and efficacy of laboratory performance requires a caseload of adequate size to maintain the skills and efficiency of the staff. Death or serious nonfatal complications of myocardial infarction and/or cerebral embolus occurs in 1.5 percent of the population examined by invasive techniques. Such problems occur 10 times more often in institutions performing fewer than 100 examinations per year than in those performing 400 examinations annually. In the interest of patient care, then, it is important to encourage optimal utilization of diagnostic resources. It is also essential that in view of the invasive nature of the cardiac catheterization procedure and the extent of possible complications associated with these procedures, cardiac surgery services must be accessible promptly, either in-house or by immediate transfer, in the event of an emergency or complication. Finally, catheterization must be performed in a laboratory that is physically part of, and is a permanent structure within, a health care facility offering inpatient support services.

(d) The standards and criteria defined in this subchapter shall apply to the efficient delivery of quality diagnostic services within the setting of the cardiac catheterization laboratory. In addition to meeting these minimal requirements, the invasive cardiac diagnostic facility is expected to operate a well-established non-invasive cardiac diagnostic laboratory. Additional requirements are set forth for the more comprehensive cardiac surgery centers and are identified within N.J.A.C. 8:33E–2.

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); in (b), rewrote last sentence; in (c), substituted "optimal" for "maximum" and deleted "the State's existing" preceding "diagnostic resources".

Case Notes

Amendment to Health Care Facilities Planning Act did not prohibit moratoria on certificate of need applications for new cardiac catheterization services. Monmouth Medical Center v. State Dept. of Health, 272 N.J.Super. 297, 639 A.2d 1129 (A.D.1994), certification denied 137 N.J. 310, 645 A.2d 138.

Amendment to Health Care Facilities Planning Act prohibited only immediate and direct implementation of specific health planning decisions. Monmouth Medical Center v. State Dept. of Health, 272 N.J.Super. 297, 639 A.2d 1129 (A.D.1994), certification denied 137 N.J. 310, 645 A.2d 138.

Imposing moratoria on consideration of certificate of need applications for cardiac services pending studies was not arbitrary and capricious. Monmouth Medical Center v. State Dept. of Health, 272 N.J.Super. 297, 639 A.2d 1129 (A.D.1994), certification denied 137 N.J. 310, 645 A.2d 138.

Hospital was granted certificate of need to construct a new cardiac catheterization laboratory. Pascack Valley Hospital v. Department of Health, 95 N.J.A.R.2d (HLT) 9.

Application of hospital for certificate of need could not be denied without first addressing necessity of providing health care in area to be served. Pascack Valley Hospital v. Department of Health, 95 N.J.A.R.2d (HLT) 5.

8:33E–1.2 Definitions

For the purposes of this subchapter, the following definitions shall apply:

"Cardiac catheterization" means the insertion of a thin, flexible tube (catheter) into a vein or artery and guiding it into the heart for purposes of determining cardiac anatomy and function.

"Cardiac surgery center" refers to a facility capable of providing invasive diagnostic catheterization, and all treatment modalities including open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG) surgery, PTCA and complex EPS studies.

"Complex Electrophysiology Study" (EPS): Refers to the more complex variety of electrophysiology study and includes:

Procedures which intend to induce ventricular or supraventricular tachycardia;

Activation sequence mapping of cardiac tachyarrhythmias;

Electrode catheter ablative procedures;

Implantation of anti-tachyarrhythmia devices and implantable cardioverter defibrillators.

These complex procedures are in contrast to non-complex electrophysiologic procedures, which primarily involve His–Purkinje conduction evaluation without arrhythmia induction.

"Coronary artery bypass graft" surgery (CABG) means a surgical procedure to treat narrowing or stenosis of the coronary arteries. The procedure is performed by a cardiothoracic surgeon who creates bypasses around the obstructions in the coronary arteries with arteries or veins from elsewhere in the body to improve blood flow to the heart (that is, revascularization of the myocardium).

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without surgery backup. These facilities have laboratories which must meet the requirement of procedures performed on at least 500 patients annually.

"Hospital–based" means the provision of a health care service that is physically located on the campus of, and is a permanent structure within, a licensed acute care hospital offering inpatient support services.

"Left–heart catheterization" refers to the measurement of left heart hemodynamics and definition of left heart anatomy/function by catheter delivered radiopaque contrast media.

"Low risk cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services within its permanent structure as defined in "hospital-based" above that is limited in the provision of its service to low risk adult patients. Patients with the following conditions listed below are to be considered high-risk and shall be excluded from catheterization at pilot facilities and transferred in accordance with N.J.A.C. 8:33E–1.8:

1. Left main coronary syndrome;
2. Unstable myocardial infarction;
3. Acute myocardial infarction within three days;
4. Unstable angina with persistent angina;
5. Congestive heart failure, defined as NYHA Class III or IV;
6. Cardiogenic shock or severe hemodynamic instability;
7. Aortic stenosis, as measured by Doppler mean gradient over 40 mm of HG;
8. Ejection fraction below 30 percent; or
9. Concomitant severe medical or vascular problems.

"Low-risk patients" shall be defined by the November 1, 1994 participation guidelines of the American College of Cardiology's Database Committee and "low-risk patients" are those patients excluded from the definition of "high-risk" who are able to be managed by the low risk facilities for diagnostic cardiac catheterization.

"Medically underserved" means segments of the population whose utilization of health care services is less than those numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services. Medically underserved includes, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"Normal coronary study" means a clinical finding subsequent to the performance of a cardiac catheterization procedure indicating less than 50 percent stenosis in all of the following arteries: left main, proximal left anterior descending (LAD), other LAD, right coronary artery (RCA) or circumflex. Any stenosis of greater than or equal to 50 percent is considered an abnormal cardiac catheterization study. A finding of valvular disease, cardiomyopathy or congenital disorders are to be considered as abnormal findings in a study.

"Open heart surgery" refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalic conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric cardiac surgery centers" are those cardiac surgery centers specifically designated to provide the full range of invasive cardiac diagnostic, therapeutic and surgical services to patients less than 16 years of age.

"Percutaneous transluminal coronary angioplasty (PTCA) or balloon angioplasty" means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PTCA also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional laser and arterial stenting procedures).

"Primary angioplasty" means the mechanical reopening of an occluded vessel using a balloon-tipped catheter in patients with acute myocardial infarction (AMI) who have not received antecedent thrombolytic therapy.

"Stent procedure" means the use of a wire mesh tube (a stent) to prop open an artery that has recently been cleared using coronary angioplasty. The stent is collapsed to a small diameter, placed over an angioplasty balloon catheter and moved into the area of the blockage. Once the balloon is inflated, the stent expands, locks in place and forms a permanent scaffold to hold the artery open. Stents may be used as an alternative to—or in combination with—angioplasty.

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.

8:33E–1.3 General criteria for invasive cardiac diagnostic facilities

(a) For the purpose of certificate of need application and licensure, invasive cardiac diagnostic facilities shall be categorized as follows:

1. Cardiac surgery center;
2. Full service cardiac catheterization facility (without cardiac surgery);
3. Low-risk diagnostic cardiac catheterization facility; and
4. Pediatric cardiac surgery center.

(b) All cardiac catheterization procedures, regardless of the category, shall be performed in a hospital-based facility where inpatient services are available on site.

(c) Only facilities with invasive cardiac diagnostic and pediatric cardiac surgery programs shall be licensed to perform invasive cardiac diagnostic procedures on pediatric patients.

(d) Complex electrophysiology studies (EPS) and/or percutaneous transluminal coronary angioplasty (PTCA) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing complex EPS and/or PTCA shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E–2.3(d).

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (a)2, substituted "Full service cardiac" for "Cardiac"; rewrote (a)3.; in (d), substituted "Complex electrophysiology" for "Electrophysiology" and inserted "complex" preceding "EPS".

Case Notes

Denial of certificate of need application for pediatric invasive cardiac diagnostic and surgery services was reversed when underutilization of nearby provider was found to be due to reluctance of physicians to refer patients to that provider. St. Joseph's Hospital v. Health Care Administration Board, 96 N.J.A.R.2d (HLT) 103.

Denial of Certificate of Need for cardiac-catheterization laboratory was not arbitrary or capricious. Pascack Valley Hospital v. New Jersey Department of Health. 93 N.J.A.R.2d (HLT) 21.

8:33E–1.4 Utilization criteria for invasive cardiac diagnostic facilities

(a) Utilization criteria for all invasive cardiac diagnostic facilities are based on the number of patients upon whom invasive cardiac diagnostic procedures (cardiac catheterization) are performed.

(b) Except as specifically set forth with respect to low risk cardiac catheterization facility, at (c) below, all facilities licensed to provide full service invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per full service cardiac laboratory is 500 per year. New full service providers (those previously operating as low risk cardiac catheterization laboratories) must provide documentation of full compliance with the minimum utilization level during their second year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Existing full service invasive cardiac diagnostic providers (with or without cardiac surgery on site) must achieve minimum utilization levels each year. 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. Those new and existing full service laboratories unable to achieve the minimum level as set forth in this paragraph will be required to submit to the following:

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

ii. A detailed plan of correction shall be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in (b)1 above and physician volume standard in (b)2 below. Where applicable, plans of correction shall be submitted 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 shall not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall 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 shall 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 shall 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.

2. Each physician must perform procedures on a minimum of 50 patients a year with a minimum of 100 patients over a two year period. (This minimum caseload may be accomplished at more than one laboratory in or out of State). For the Director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the full service laboratory of which the physician is Director.

"Open heart surgery" refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalic conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric cardiac surgery centers" are those cardiac surgery centers specifically designated to provide the full range of invasive cardiac diagnostic, therapeutic and surgical services to patients less than 16 years of age.

"Percutaneous transluminal coronary angioplasty or balloon angioplasty" (PTCA) means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PTCA also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

"Primary angioplasty" means the mechanical reopening of an occluded vessel using a balloon-tipped catheter in patients with acute myocardial infarction (AMI) who have not received antecedent thrombolytic therapy.

"Satellite hospital" means a noninner city licensed acute care hospital which is a member of a hospital system containing an inner city teaching hospital and which is permitted to provide invasive therapeutic cardiac services through implementation of an inner city cardiac satellite demonstration project, in accordance with this chapter.

"Stent procedure" means the use of a wire mesh tube (a stent) to prop open an artery that has recently been cleared using coronary angioplasty. The stent is collapsed to a small diameter, placed over an angioplasty balloon catheter and moved into the area of the blockage. Once the balloon is inflated, the stent expands, locks in place and forms a permanent scaffold to hold the artery open. Stents may be used as an alternative to—or in combination with—angioplasty.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote "Cardiac surgery center" definition; and inserted new "Hospital system", "Inner city cardiac satellite demonstration project", "Inner city hospital", "Invasive therapeutic cardiac services" and "Satellite hospital" definitions.
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.

8:33E–2.3 Utilization of cardiac surgical centers

(a) The following shall apply to adult cardiovascular surgical units:

1. An applicant for a certificate of need to initiate adult cardiac surgery services shall provide written documentation of the ability to achieve an annual volume of 350 open heart surgical cases by the end of the third year of operation and annually thereafter.

2. All existing regional adult cardiac surgical centers shall continue to perform at least 350 open heart surgical procedures per year to insure the competency of the surgical services team and to provide for efficient and economical operation. Compliance with this annual facility volume requirement shall be calculated on the basis of the last four quarters of data submitted to and reviewed by the Department prior to the facility's licensure anniversary date.

3. Each cardiac surgical center shall establish a minimum caseload per physician in order to ensure a consistent level of proficiency within the surgical program. A minimum of 100 cases per year shall be performed by each cardiac surgeon performing as the primary surgeon on any case. This volume shall be achieved at each licensed site in New Jersey at which the physician practices as primary surgeon on any case. Compliance with annual physician volume standards shall be calculated on a calendar year basis.

(b) The following shall apply to pediatric cardiac diagnostic and surgical services:

1. An applicant for a certificate of need as a regional pediatric cardiac surgical center shall provide written documentation that the proposed center will perform at least 150 pediatric open and closed heart surgery procedures per year, at least 75 of which must be open heart procedures, for each operating room utilized for pediatric open heart surgery by the end of the third year of operation and each year thereafter.

2. A regional pediatric cardiac surgical center shall continue to perform at least 150 pediatric open and closed heart surgery procedures per year per operating room to insure the competency of the pediatric surgical services team and to provide for an efficient and economical operation. Existing pediatric cardiac surgical centers shall achieve this utilization standard within one year of the effective date of this subchapter and shall maintain the standard on an annual basis thereafter.

3. The minimum acceptable number of pediatric cardiac catheterization patients per invasive pediatric cardiac diagnostic laboratory is 150 per year. New pediatric surgical centers shall achieve this minimum level of utilization in their invasive pediatric cardiac diagnostic laboratory within three years from the initiation of the service. As cited at N.J.A.C. 8:33E–1.2(e), pediatric patients requiring invasive cardiac diagnostic procedures shall undergo these procedures only in centers with invasive pediatric cardiac diagnostic and pediatric cardiac surgery programs.

4. Each invasive pediatric cardiac laboratory shall establish a minimum number of procedures for each physician with laboratory privileges in order to maintain a consistent level of proficiency within the laboratory. A minimum of 50 pediatric cases a year with a minimum of 100 pediatric cases over a two year period shall be maintained to preserve a consistent level of proficiency.

(c) The following shall apply to adult full service cardiac diagnostic services located within the cardiac surgery center:

1. In accordance with N.J.A.C. 8:33E–2.1(c) and except as specifically set forth at N.J.A.C. 8:33E–2.3(d) through (e), 2.4(d) through (f), 2.10 and 2.14 the provision of adult full service cardiac diagnostic services by cardiac surgery centers shall be subject to all applicable utilization criteria at N.J.A.C. 8:33E–1.

2. The laboratory must be prepared to perform pre- and post-operative examinations on a scheduled basis, and emergency examinations at all times.

3. As a planning guideline, the accepted ratio of examinations to cardiac operations shall be at least two examinations to one operation.

(d) The following shall apply to adult cardiac surgery centers providing or seeking to provide percutaneous transluminal coronary angioplasty (PTCA) services:

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide PTCA services in its invasive cardiac diagnostic laboratory must provide written documentation that the center will perform a minimum of 200 PTCA procedures per year by the third year of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels during the third year of operation or thereafter shall be required to submit to the process that has been established at (d)2 below.

2. A regional adult cardiac surgery center shall continue to perform a minimum of 200 PTCA procedures annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing PTCA shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for PTCA shall be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter shall be required to submit to the following:

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

ii. A detailed plan of correction shall be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in (d)1 or 2 above, whichever is applicable, and physician volume standard in (d)4 below. Where applicable, plans of correction shall be submitted 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 shall 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 shall not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall 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 shall 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 shall 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.

3. With the exceptions of any waiver granted before January 1, 2001 and of any trial program approved pursuant to N.J.A.C. 8:33E–2.16, PTCA procedures shall be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

4. Each PTCA facility shall establish a minimum number of PTCA procedures for each physician with PTCA laboratory privileges. Each physician performing PTCA procedures as the primary operator shall perform a minimum of 75 PTCA cases a year, 150 PTCA cases over a two year period (excluding the physician's first year of clinical practice following completion of training). Compliance with annual physician volume standards shall be calculated on a calendar year basis.

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform PTCA, physician not a member of the staff for an entire year, or new program in operation less than one year, require only timely written notification to the Department. Any other extraordinary circumstances shall require the submission by the hospital of a written waiver request in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G–2.8. Compliance with physician volume standards shall be calculated on a calendar year basis.

(e) The following shall apply to adult cardiac surgery centers providing or seeking to provide complex electrophysiology studies (EPS):

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide complex electrophysiology studies or an existing, cardiac surgery center seeking to initiate complex electrophysiology services must provide written documentation that the center will perform a minimum of 100 electrophysiology studies per year, with at least 50 of these studies representing initial studies of patients. These new complex electrophysiology services must achieve this minimum utilization level within three years of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels during the third year of operation or thereafter shall be required to submit to the identical process that has been established at (e)2 below.

2. A regional cardiac surgery center shall continue to perform a minimum of 100 complex electrophysiology studies annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing complex electrophysiology studies shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for complex EPS shall be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter shall be required to submit to the following:

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

ii. A detail plan of correction shall be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in (e)1 or 2 above, whichever is applicable, and physician volume standard in (e)4 below. Where applicable, plans of correction shall be submitted 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 shall 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 shall not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall 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 shall 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 shall 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.

3. Complex electrophysiology studies shall be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

4. Each complex electrophysiology service shall establish a minimum number of complex electrophysiology studies for each physician with electrophysiology laboratory privileges. A minimum of 50 complex electrophysiology cases a year, with at least 25 as initial studies, shall be maintained to preserve a consistent level of proficiency. Compliance with annual physician volume standards shall be calculated on a calendar year basis.

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform complex EPS, physician not a member of the staff for an entire year, or new program in operation less than one year, require only timely written notification to the Department. Any other extraordinary circumstances shall require the submission of a written waiver request by the hospital in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G–2.8. Compliance with physician volume standards shall be calculated on a calendar year basis.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
In (a), rewrote 1, substituted "350" for "250" following "at least" in 2, deleted former 3 and 4, and rewrote and recodified former 5 as 3; and in (e)1, substituted "operation" for "service implementation" at the end.

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.

8:33E–2.4 Cardiac surgery center personnel

(a) The following shall apply to cardiovascular surgical units:

1. Cardiac surgery is most successful when performed by a smoothly functioning team. The basic team of the regional cardiac surgical center shall consist of the following permanently assigned staff:

i. One physician in charge of the operation (that is, primary surgeon), board-certified by the American Board of Thoracic and Cardiovascular Surgery as a cardiovascular surgeon who directs the team or the surgical unit. A minimum of 100 cases per year shall be performed by each cardiac surgeon as the primary surgeon on any case. This volume shall be achieved at each licensed site in New Jersey at which the physician practices as primary surgeon on any case;

(1) Exceptions for incumbent directors to this requirement for board certification may be granted by the Commissioner and upon application by an institution providing proper documentations as to the physician's qualifications;

(2) Exceptions for surgeons to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform surgery, physician not a member of the staff for an entire year, or new program in operation less than one year, require only timely written notification to the Department. Any other extraordinary circumstances shall require the submission of a written waiver request by the hospital in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G–2.8. Compliance with physician volume standards shall be calculated on a calendar year basis.

ii. One assistant to the physician in charge of the operation who will be a board qualified surgeon. A cardiothoracic surgery resident or fellow may serve as an assistant. There shall be two surgeons in the operating room;

iii. An anesthesiologist, meeting the licensing requirements contained at N.J.A.C. 8:43G–7.5(c)1 and 2 shall be responsible for the anesthetic management of cardiac surgery patients. This anesthesiologist may be assisted by additional personnel as specified at N.J.A.C. 8:43G–7.5(d);

iv. There shall be at least one registered nurse and an assistant meeting licensing requirements at N.J.A.C. 8:43G–7.5(h) in each operating room;

v. In accordance with N.J.A.C. 8:43G–7.5(i), a perfusionist who is certified by the American Board of Cardiovascular Perfusion or meets the experience requirements shall be available to operate the perfusion pump for each cardiac surgical procedure. A second perfusionist meeting the same requirements shall be available in the surgical suite to assist. In emergency cases, a second perfusionist may be off-site and readily summoned if needed;

vi. A cardiovascular nurse specialist (one for every 100 open heart procedures) and a physician's assistant may be employed to supplement the cardiovascular surgical team.

vii. A board certified cardiologist shall be available to assist in the management of problems relating to unstable hemodynamic status and complex arrhythmias, if necessary.

2. The primary operating cardiac surgeon, in conjunction with the attending cardiologist, shall be responsible for overseeing and integrating all details of pre-operative evaluation and preparation of the operation procedures and of postoperative care.

(b) The intensive care cardiac recovery room (or Surgical Critical Care Unit (SCCU)) is the area where cardiac patients are held for postoperative care. At a minimum, patient coverage in this area shall be on a one specially trained cardiac nurse to one patient basis for the first 24 hours after surgery or in accordance with the diagnosis. During this period of intensive care, the operating surgeon and team or qualified alternate shall be on call. Clinical appropriateness may permit the patient to be transferred sooner than 24 hours to a step-down unit where the above 1:1 nursing to patient ratio does not apply. After a full 24 hours following the operative day, and in accordance with patient diagnosis, nursing coverage may be reduced to a maximum of three patients to two nurses during the second and third days following the operative day as long as ventilatory and other life support systems have been discontinued.

1. It is recommended that there be at least six surgical intensive care beds for each operating room within the surgical center that is dedicated to open heart surgery patients.

2. The surgical intensive care unit shall include physiologic monitoring equipment capable of arrhythmia detection (including slave scopes). Portable x-ray equipment and computers for laboratory work should also be available.

(c) The following shall apply to cardiac diagnostic facilities located in a cardiac surgery center.

1. Except as specifically set forth below in accordance with N.J.A.C. 8:33E–2.1(c), the provision of cardiac catheterization services by regional cardiac surgery centers shall be subject to all facility personnel requirements for such services as set forth at N.J.A.C. 8:33E-1.5.

2. Exceptions to these minimum training and certification requirements for incumbent directors and associate physicians may be granted by the Commissioner and upon application by an institution providing proper documentation as to the physician's qualifications, in accordance with the requirements of this chapter, N.J.A.C. 8:43G–7.15(b), 7.40 and 7.28, and N.J.A.C. 13:35.

(d) Only the special personnel required by a cardiac diagnostic center established within an existing hospital are specified in (c) above. Appropriate supporting staff or personnel shall be available in existing departments within the hospital, in accordance with the requirements of all applicable laws, rules and regulations.

(e) The following shall apply to invasive cardiac diagnostic facilities located in cardiac surgery centers that seek to perform percutaneous transluminal coronary angioplasty (PTCA):

1. Each invasive diagnostic facility must be staffed, at a minimum, by the following personnel during a PTCA procedure:

i. The physician directing the procedure shall be a board certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization and who has participated in a minimum of 100 PTCA procedures (with at least 50 as primary operator) and meets the licensing qualifications specified at N.J.A.C. 8:43G–7.23(a);

ii. An assisting physician, if needed, may be a board-certified or board-eligible cardiologist or a cardiology fellow;

iii. A registered nurse meeting the licensing requirements specified at N.J.A.C. 8:43G–7.24(a)2 shall be available to assist with PTCA procedures; and

iv. One assistant meeting the licensing requirements specified at N.J.A.C. 8:43G–7.24(a)3 shall be available to assist with PTCA procedures.

(f) The following shall apply to invasive cardiac diagnostic services located in cardiac surgery centers that seek to perform complex electrophysiology studies (EPS):

1. Each invasive cardiac diagnostic service shall be staffed, at a minimum, by the following personnel during a complex electrophysiology study.

i. The physician directing the procedure must be a board-certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization who has obtained at least one additional year of specialized training in complex EPS and cardiac arrhythmias including participation in 100 complex EPS procedures, and meets the licensing qualifications specified at N.J.A.C. 8:43G–7.26(a).

ii. An assisting board-certified or board-eligible cardiologist, if needed, shall be present during complex EPS procedures.

iii. A registered nurse meeting the licensing requirements specified at N.J.A.C. 8:43G–7.27(a)2 shall be present during the procedure.

iv. One assistant meeting the licensing requirements specified at N.J.A.C. 8:43G–7.27(a)3 shall be present during the procedure.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote (a).
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.

8:33E–2.5 Use of inpatient facilities

(a) In a center performing 350 open heart surgical cases annually, the following inpatient facilities shall be required:

1. An intermediate intensive care/cardiac care unit will be available for post-operative care. It shall include four beds for patients having an average length of stay of three to four additional days following discharge from the SCCU or surgical recovery room. These beds may be located in a cardiovascular step-down unit with telemetry monitoring but reduced nursing coverage consistent with licensing requirements at N.J.A.C. 8:43G–9.20 and in accordance with patient diagnosis. Suitably equipped beds will be available for the rest of the patient's stay. At a minimum the intensive care/cardiac care unit will have the following capabilities:

i. Facilities for hemodynamic ECG monitoring;

ii. Temporary pacemaker insertion;

iii. C.P.R. equipment;

iv. Arrhythmia detection equipment;

v. Resuscitative equipment; and

vi. Cardiovascular support devices (such as an intra-aortic balloon pump).

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
In the introductory paragraph of (a), changed the required annual number of open heart surgical cases from 250 to 350.

8:33E–2.6 Commissioner's cardiovascular health advisory panel (CHAP)

(a) A cardiovascular health advisory panel has been established, under the authority of the Commissioner of Health and Senior Services to provide the Commissioner with expert clinical and/or technical advice required for the

development of sound cardiovascular health policy. The committee panel shall also:

1. Assist in the development of Statewide cardiovascular health promotion and disease prevention activities;

2. Review cardiac service technological developments and provide advice on the degree to which these developments have been integrated into the accepted standards of practice;

3. Provide advice on implications of changes in technology and/or patterns of practice for State standards and criteria for cardiac services;

4. Advise on Statewide issues regarding cardiac care; and

5. Advise on the development and implementation of Statewide cardiac research and data activities.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Changed references to the Commissioner of Health to references to the Commissioner of Health and Senior Services throughout.
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.

8:33E–2.7 Referral

(a) Each applicant for a certificate of need as a regional cardiac center shall agree to send out a mailing to all appropriate institutions and physicians stating that the services of the center are available. Following certificate of need approval, the center shall provide the Department with written documentation that this mailing has occurred.

(b) Each applicant shall provide written documentation, in the form of an institutional policy statement, that the center will accept referrals from physicians not ordinarily having access to the applicant's facilities.

(c) Each center will have written transfer agreements to receive appropriate patients from the invasive cardiac diagnostic facilities in its service area, or health services area, whichever is larger.

8:33E–2.8 (Reserved)

8:33E–2.9 Documentation of purchase and operational cost

The applicant will provide full written documentation of the projected implementation and operational costs of the proposed program. This documentation will include direct and indirect costs, that is, construction, equipment, supplies, personnel, maintenance, overhead costs, as well as projected costs of remodeling or renovation necessary to accommodate the program. Projections of anticipated revenues shall be supplied for at least the first three years.

8:33E–2.10 Data to be maintained and reported

(a) Every cardiac facility licensed to provide therapeutic interventional cardiac-procedures that include, but are not limited to, cardiac surgery and PTCA or coronary angioplasty services in accordance with this subchapter shall maintain and provide data on patient characteristics and outcomes, services to medically underserved populations, community outreach, and individual program components as determined by the Department. All hospitals shall report these data to the Department of Health and Senior Services on a quarterly basis and in a standardized format determined by the Department. If necessary to determine whether a facility is in compliance with this chapter, the Department shall require that the data submitted shall be audited at the hospital's expense by an independent third party approved by the Department.

1. The criteria for auditor approval are as follows:

i. All potential auditing firms shall document their experience in medical record review. Prior to approval by the Department, an auditing firm shall submit three references from entities for which it has performed medical record reviews within the past five years. Prior experience does not necessarily have to pertain to cardiac care.

ii. Auditing firms shall be independent from the facility being audited. To be independent, an auditor shall have no financial or familial interest in the facility being audited. Auditors shall be independent both in fact and in appearance. Further, the auditor shall not have had any involvement in the audited facility's cardiac surgery center certificate of need application.

iii. Auditing firms shall submit the names and qualifications of all staff assigned to the relevant audit team. Staff who review the medical records and determine the accuracy of data submitted to the Department shall include at least one registered nurse trained and experienced in assisting invasive cardiac therapeutic procedures. In addition, the audit team shall include at least one accredited records technician or a registered record administrator accredited under a certification program approved by the American Medical Records Association. Other staff shall have experience either in medical record review or with the provision of invasive cardiac therapeutic procedures.

iv. Auditing firms shall identify and contract with at least two board certified cardiologists then in practice to review data from which medical diagnoses are made. The two cardiologists shall not be on staff at the audited facility. They shall be certified by the Cardiovascular Sub-Specialty Board of the American Board of Internal Medicine. They shall have broad experience and training in invasive cardiac therapeutic procedures, including, but not limited to, a minimum of 12 months in an invasive therapeutic cardiac services program and the performance of at least 200 invasive cardiac therapeutic procedures, with 100 of those procedures performed as the head cardiologist.

v. Any change in audit firms by an audited facility shall be approved by the Department based upon the criteria set forth in this section. Additionally, any change in personnel of the relevant audit team shall be done in accordance with the standards as set forth in this section and reported to the Department.

vi. All employees of the audit firm with access to confidential data shall sign a confidentiality assurance statement with the audited facility prior to access to the confidential data.

2. Patient level data shall be submitted to the Department of Health and Senior Services on a quarterly basis, within 30 days after the close of the quarter. These patient care and outcome data shall include, but not be limited to, mortality and morbidity information and other information relative to the specific cardiac surgery center, as determined by the Department. Copies of the full text of the required quarterly reporting forms may be obtained upon written request to:

The New Jersey State Department of Health and Senior Services
Division of Health Care Systems Analysis
Research and Development Program
PO Box 360
Trenton, New Jersey 08625–0360

3. All hospitals shall report to the Department information regarding their respective outreach and services to medically underserved populations in their respective catchment or service area. Data shall include, but not be limited to, numbers of patients served by race/ethnicity, income, outreach to minority and indigent groups, and preventive and primary care services to medically underserved groups.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote (a).
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (a), inserted "PTCA or" preceding "coronary angioplasty" and "characteristics and" preceding "outcomes"; deleted (b).

8:33E–2.11 Certification of nondiscriminatory practices

Each applicant shall provide the Department with written certification of compliance with all Federal and State laws in regard to nondiscriminatory practices to the effect that no patient shall be refused treatment on the basis of race, religion, sex, age or ability to pay.

8:33E–2.12 Quality improvement

(a) Quality control is essential for the consistent high quality level of performance required of any medical services. As one means of quality control, appropriate mechanisms for peer review shall be described in each application for designation as a cardiac surgical center. Such mechanisms should include, but not be limited to, the delineation of criteria for the evaluation of:

1. Overall case selection for study (for example, rate of normal studies, rate of surgical referral);

2. Laboratory and physician performance including the physician performance guidelines (for example, case volume, mortality and complication rates per physician);

3. Quality of studies (for example, number of incomplete studies, diagnostic adequacy of films, number of restudies performed elsewhere); and

4. Surgical program performance (including case volume, mortality, complication rate, rate of emergency surgery following unsuccessful PTCA and reoperations).

(b) In all cases, criteria selection should be based on sound medical practice and consistency with the literature. Internal quality assurance procedures shall be adopted to address patient safety issues and the clinical appropriateness of the services being provided.

(c) All cardiac surgical centers shall participate in a continuous quality improvement (CQI) program that meets nationally recognized standards for improvement in cardiovascular care.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
In (a), substituted "surgical center" for "diagnostic facility" in the introductory paragraph; and added a new (c).
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (a)2, deleted "as recommended by the Cardiac Service Task Force" following "performance"; added (a)4.; rewrote (b).

8:33E–2.13 Compliance

(a) Existing pediatric and adult cardiac surgery centers shall continue to meet the minimum criteria and standards contained in this subchapter on an annual basis. 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. Those existing cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter shall 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;

2. A detailed plan of correction shall be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standards in N.J.A.C. 8:33E–2.3(a)2 and physician volume standards in N.J.A.C. 8:33E–2.3(a)3. Where applicable, plans of correction shall be submitted 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 shall not be considered final until it has been approved by the Department;

3. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall 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 shall 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 shall be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

i. The scope and severity of the threat;

ii. The frequency of the occurrence;

iii. The presence or absence of attempts at remedial action by the facility;

iv. 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

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

(b) All certificate of need applications for new pediatric and adult cardiac surgery centers must document the ability of the applicant to meet the minimum standards and criteria contained in this subchapter in accordance with N.J.A.C. 8:33E–2.14 or 2.15, as applicable. The inability to achieve minimum utilization levels during the third year of operation or thereafter will be required to submit to the identical process that has been established at (a) above.

(c) Notwithstanding the duration of unimplemented certificates of need criteria as set forth at N.J.A.C. 8:33–3.10, all certificate of need applications for new pediatric and adult cardiac surgery services approved after the effective date of these rules shall have two years from the date of certificate of need approval to initiate such services by obtaining licensure approval. In accordance with N.J.A.C. 8:33–3.10(a)4, failure to implement the project within two years shall result in the automatic termination of the certificate of need, unless the Commissioner determines that the failure of the applicant to complete the project within the time frame was the result of extraordinary unforeseeable circumstances beyond the control of the applicant. In accordance with N.J.A.C. 8:33–3.10(a), extension of time requests shall be filed within 60 days prior to the current certificate of need expiration date and shall include detailed documentation of the following:

1. The current status of the project;

2. The reasons for the delays; and

3. A proposed detailed time frame identifying the remaining time needed for the project to be licensed by the Department's Certificate of Need and Acute Care Licensure Program.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
In (a), deleted "reimbursement or" preceding "licensing sanctions"; and rewrote (b).
Recodified from N.J.A.C. 8:33E–2.14 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 section. Former N.J.A.C. 8:33E–2.13, New facilities; diagnostic pilot cardiac catheterization programs at cardiac surgery centers, repealed.

8:33E–2.14 Submission of Certificate of Need applications

(a) In accordance with N.J.A.C. 8:33E–2.1(c), all certificate of need applications by regional cardiac surgery centers for invasive cardiac diagnostic services shall be subject to the applicable requirements of N.J.A.C. 8:33E–1.11 and 1.12.

(b) All certificate of need applications seeking to initiate cardiac surgical services shall be subject to the requirements of this subchapter, as applicable, and the following:

1. The Department shall only process certificate of need applications for the initiation of cardiac surgical services in accordance with procedures set forth below and in N.J.A.C. 8:33. Certificate of need applications shall only be accepted for processing from acute care hospitals that meet the following criteria:

i. The applicant has 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 with cardiac licensing requirements at N.J.A.C. 8:43G–7, for the previous three calendar years prior to the submission of the application; and

ii. The applicant shall identify specific minority and medically underserved populations residing in the communities in its service area that shall be targeted for improved access to preventive, diagnostic and therapeutic cardiovascular service delivery.

2. All applicants shall document their cardiovascular disease (CVD) community prevention services for all populations, specifically targeting minorities and indigent population groups. Examples of community prevention programs are those primary and secondary prevention initiatives which include: diet and drug therapy for hypercholesterolemia in patients at high risk or with established coronary artery disease; smoking cessation programs with objective outcome measures; exercise rehabilitation programs for patients with established coronary artery disease; and public education programs.

i. The applicant shall document the current availability and utilization of its cardiology and/or cardiovascular disease clinic services, particularly with respect to its historic provision of services to the indigent and medically underserved populations within its service area;

3. All applicants shall provide a plan, as part of their application, that is designed to ensure that appropriate access to both the diagnostic and therapeutic cardiac interventions by medically underserved and minorities (for example, African-Americans, Latino-Americans, Asian-Americans), 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 shall provide cardiac therapeutic interventions to medically underserved and minorities in comparable proportion to the general population in the hospital's service area. This plan may serve as a basis for conditions placed on certificate of need approval; and

4. All applicants shall document the proportion of Medicaid-eligible and medically underserved groups residing in the proposed service area. In addition, the applicant shall, in delivering the proposed service, provide care on a free or partial pay basis to Medicaid-eligible and medically underserved population groups at least in proportion to their representation in the proposed service area.

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.

8:33E–2.15 Competitive review criteria

(a) The Department's goal in approving additional cardiac surgery programs is to improve access to all cardiac services especially for medically underserved and minority populations. During certificate of need review, consideration for approval shall be limited to the applicant that, to a greater extent than the competing applicants, has documented compliance with the following competitive review criteria and has also documented compliance with all other applicable criteria in this subchapter and N.J.S.A. 26:2H–8.

1. The applicant is able to provide quantifiable documentation of its historic commitment to access to cardiac services, particularly with respect to invasive cardiac diagnostic services, to minority and medically underserved populations;

2. The applicant is able to provide persuasive documentation that its plan to provide appropriate access to cardiac surgery services to the medically underserved minority populations identified in the proposed service area shall be achieved;

3. The applicant is able to provide quantifiable documentation of its ability to capture referrals that are currently being made to out-of-State cardiac surgery centers;

4. The applicant is able to provide quantifiable documentation of the existence of geographic access problems for invasive therapeutic cardiac services that include, but are not limited to, factors such as distance, both in terms of mileage and average travel time, to alternate cardiac surgery centers within its region;

5. The applicant is able to provide quantifiable documentation that the initiation of its new service shall not have an adverse economic or financial impact on the provision of cardiac surgery services on existing cardiac surgery centers in the region or the delivery of health care services in the region or Statewide in accordance with N.J.S.A. 26:2H–8. If the applicant believes there shall be any such adverse impact, then the applicant shall identify quantifiable improvements in both economic and geographic access;

6. The applicant is able to provide quantifiable documentation that the hospital's admissions for acute myocardial infarction (AMI), during the time period specified in the call, is no more than 10 percent below the Statewide mean;

i. The documentation required by this paragraph shall be limited to the licensed hospital site at which the proposed surgical center shall be located;

7. The applicant is able to document that it is located in a county in which, for the time period specified in the call, more than 25 percent of the residents of the county in which the hospital is located who were diagnosed with an AMI, migrated outside the county for that diagnosis; and

8. The applicant is able to document that it is located in a county in which, for the time period specified in the call, residents underwent open heart surgery outside their county in a substantially greater proportion than residents of other counties in the State.

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.

8:33E–2.16 Limited PTCA trial programs

(a) At the discretion of the Commissioner, the Department may invite applications from facilities seeking to provide PTCA services in emergent situations without the availability of on-site cardiac surgery.

1. Any such application shall be accepted only from facilities that have a full service adult diagnostic cardiac catheterization program that has documented, to the satisfaction of the Department, 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 using audited data.

(b) Permission to provide PTCA services in emergent situations without the availability of on-site cardiac surgery shall be granted in the form of a waiver of N.J.A.C. 8:33–2.3(d)3 and shall be limited as follows:

1. The waiver shall be in writing, signed by the Commissioner;

2. The Commissioner shall grant no more than two waivers pursuant to this section;

3. Exceptions to the on-site cardiac surgery backup requirement are limited to the performance of non-elective, primary angioplasty on patients with acute myocardial infarction (AMI) that are not able to be transferred safely to an established cardiac surgery center on a timely basis, are at least 18 years old, and are developing hypotension, congestive heart failure, or are in frank cardiogenic shock, or meet the following criteria:

i. Presentation 12 hours or less from the onset of AMI;

ii. History at presentation of chest pain lasting thirty minutes or longer; and

iii. ECG showing persistent:

(1) Greater than or equal to 0.1 mV ST elevation in two or more limb leads;

(2) Greater than or equal to 0.1 mV ST elevation in two or more contiguous precordial leads;

(3) Greater than or equal to 0.1 mV ST depression in V_{1-2} secondary to posterior infarction; or

(4) Left bundle branch block; and

iv. Chest pain and ST-segment changes do not resolve with nitroglycerin;

4. Physicians and support staff performing PTCA services at the facility shall meet the minimum requirements for the performance of PTCA procedures as set forth at N.J.A.C. 8:33E–2.4(e) and N.J.A.C. 8:43G–7.29 and 7.30; and

5. Any waiver granted shall be immediately revocable if the Commissioner finds that the trial program is not meeting standards set forth in its application or established by the Commissioner's approval letter.

(c) The following criteria shall be considered by the Commissioner in determining whether to grant a waiver:

1. The ability of the facility requesting the waiver to perform at least 17 to 48 PTCA procedures per year;

2. The ability of the facility requesting the waiver to have immediately on site and available emergency transport equipped to accommodate a balloon pump;

3. The existence of an executed affiliation and transfer agreement as required by N.J.A.C. 8:33E–1.8;

4. Proximity to existing licensed cardiac surgery centers; and

5. Such other considerations as the Commissioner deems appropriate.

(d) In order to facilitate the Department's review of the safety and effectiveness of allowing for the provision of emergency PTCA at licensed full service adult diagnostic cardiac catheterization facilities, the Department shall:

1. Consistent with N.J.A.C. 8:33E–2.10, develop quarterly reporting requirements for facilities performing emergency PTCA procedures under this waiver;

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 waivered facility pursuant to N.J.A.C. 8:33E–1.9;

3. Determine whether to expire the emergency PTCA waivers, continue the emergency PTCA waivers at the existing facilities, or expand the emergency PTCA waiver to additional facilities. This determination shall be made:

i. Upon the Department's receipt of eight fully documented quarterly reports from each waivered facility; and

ii. In consultation with the CHAP, and in view of any changes in recommended guidelines published by the American College of Cardiology/American Heart Association.

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.