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 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) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing complex EPS shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E–2.3(d). Elective PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent) PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E–2.16.

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" and rewrote (a)3; in (d), substituted "Complex electrophysiology" for "Electrophysiology" and inserted "complex" preceding "EPS".
Amended by R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Rewrote (d).

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.

i. Exceptions for cardiologists to the minimum director and physician volume requirements may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform cardiac catheterization, 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.

(c) All facilities licensed to provide invasive cardiac diagnostic services pursuant to low risk catheterization facility standards described in this subchapter 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 year is 350. Those laboratories unable to achieve this minimum level by the end of the second year of operation as set forth at N.J.A.C. 8:33E–1.13, 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 (c)1 above and physician volume standard in (c)2 below. Where applicable, plans of correction shall be submitted indicating what licensure renewal criteria are deficient, what corrective actions are to be put in place or what systemic changes 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. Physicians practicing in hospitals operating a low risk catheterization facility shall meet minimum volume criteria. 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 low risk laboratory of which the physician is Director. For other physicians with privileges in the low risk laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory in or out of State.)

i. Exceptions for cardiologists to the minimum director and physician volume requirements may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform cardiac catheterization, physician not a member of the staff for an entire year, or new program in operation less than two years, 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.

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–1.5 Facility personnel

(a) All facilities applying to provide or providing any invasive cardiac diagnostic services pursuant to this subchapter shall provide for and maintain the following minimum staff members:

1. One physician;

2. One registered nurse; and

3. One technician who must be qualified in at least one of the technician categories listed at (b)6 through 8 below.

(b) While the following functions shall be performed within each facility, more than one function may be executed by a single individual if that individual has been appropriately cross-trained to perform the required functions:

1. The laboratory director (physician in charge) shall be the chief diagnostician within the unit, and shall be certified by the Cardiovascular Sub–Specialty Board of the American Board of Internal Medicine or by the Sub–Specialty Board of Pediatric Cardiology of the American Board of Pediatrics. In addition to Board certification, the director shall have broad experience and training in invasive cardiac diagnostic procedures, including, but not limited to, a minimum of 12 months in a cardiac catheterization training program and the performance of 200 cardiac catheterization procedures with 100 of these procedures performed as the primary operator.

2. Associate physicians may be assigned to the laboratory and shall meet the identical training requirements for laboratory director contained in (b)1 above. In addition, all catheterizing physicians shall adhere to the minimum physician volume standards established for each laboratory in accordance with N.J.A.C. 8:33E–1.4(b)2 and (c)2, whichever is applicable.

i. Exceptions to these minimum training and certification requirements for incumbent Directors and associate physicians requirements may be granted by the Commissioner upon application by an institution providing 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, 7.28, and N.J.A.C. 13:35.

3. The registered nurse shall assist with administration of medications and the preparation and observation of the patient. The nurse shall have intensive cardiac care unit (ICCU) experience, shall meet the licensing requirements specified at N.J.A.C. 8:43G–7.15(d), and shall have knowledge of cardiovascular medications, experience with catheterization and, for pediatric cardiac surgery centers, pediatric experience.

4. The cardiac catheterization technician shall handle blood samples and assist in the performance tests. The technician shall help in the maintenance of equipment and supplies and should be trained to aid in patient observation and acute cardiac care.

5. The cardiac catheterization technician shall be responsible for constant monitoring and recording of all physiologic data including the electrocardiogram.

6. The radiologic technician shall be skilled in conventional radiography and shall have special training and skills in angiographic techniques. This technician shall be competent in magnification radiography, subtraction photography, cine recording, television presentations and the use of videotape and be responsible for the care and maintenance of all radiologic equipment.

7. The electronic and radiological repair technician shall be available for consultations regarding the operation and maintenance of all radiographic and physiologic measuring and recoding instruments in the laboratory. This person shall be immediately available to carry out repairs in the event of equipment failures during the course of the procedure.

8. Hospitals providing invasive cardiac diagnostic services should, to the extent possible, have bilingual clinical personnel available who can overcome language barriers and know and understand cultural differences among patients.

(c) One physician trained and experienced in cardiac catheterization shall be present in the room during all catheterization and angiographic procedures. An appropriately trained and experienced registered nurse and technician shall also be present during all procedures.

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–1.6 Quality improvement

(a) All facilities applying to provide or providing any invasive cardiac diagnostic services pursuant to this subchapter shall provide for and shall maintain an appropriate mechanism for peer review which shall include, but not necessarily 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 physician performance guidelines (for example, patient volume, mortality and complication rates per physician); and

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

(b) In all cases, there shall be documentation that criteria selection is based on sound medical practice and consistent 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) Each peer review team shall include at least one cardiovascular surgeon from the surgical center to which surgical candidates are commonly referred.

(d) All facilities applying to provide or providing a low risk cardiac catheterization facility or a full service adult diagnostic cardiac catheterization facility shall also provide written documentation that the proposed services shall adhere to the following quality of care outcome measures:

1. A low-risk patient mortality and morbidity rate as reviewed by the hospital's peer review mechanism and submitted to the Department of Health and Senior Services for review and approval;

2. A physician-specific and overall low risk laboratory percentage of normal studies that does not exceed 25 percent of total annual cardiac catheterization cases;

3. Review by the hospital's peer review mechanism of any low risk laboratory reporting more than 50 percent increase in the number of normal studies during any quarterly reporting period and the submission to the Department within 60 days of such review of a plan for corrective action to restore normal studies to the level permitted herein;

4. The percentage of all patients undergoing diagnostic cardiac catheterization in the low risk catheterization facility who have subsequently undergone a therapeutic interventional cardiac procedure (for example, coronary angioplasty, directional atherectomy, coronary bypass surgery) as a direct result of the findings of the diagnostic cardiac catheterization procedure performed at this low risk catheterization facility will be monitored by the Department; and

5. Careful monitoring of the clinical appropriateness of the performance of right heart catheterization procedures.

(e) All facilities applying to provide or providing full service adult diagnostic cardiac catheterization services shall also provide written documentation that the proposed services shall adhere to the following quality of care outcome measures:

1. A full service patient mortality and morbidity rate as reviewed by the hospital's peer review mechanism and submitted to the Department of Health and Senior Services on a quarterly basis for review and approval; and

2. The percentage of all patients undergoing diagnostic cardiac catheterization in the full service catheterization program who have subsequently undergone a therapeutic interventional cardiac procedure (for example, coronary angioplasty, directional atherectomy, coronary bypass surgery) as a direct result of the findings of the diagnostic cardiac catheterization procedure performed at this full service catheterization program shall be monitored by the Department.

Amended by R.2001 d.210, effective June 18, 2001.

See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote (b) and (d); added (e).

8:33E–1.7 Community outreach, access and prevention

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter shall develop and maintain appropriate mechanisms to assure access to services and to promote cardiac health among the underserved population in its service area which shall include, but not necessarily be limited to, the following components:

1. All hospitals, including those participating as a low risk catheterization facility, shall document their community prevention services for all populations, specifically targeting minorities, elderly and under–12 population groups, in accordance with license renewal standards at N.J.A.C. 8:33E–1.13 and 1.14. 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.

2. All hospitals, including those participating as a low risk catheterization facility, shall provide a plan, as part of their application that is designed to ensure that appropriate access to their respective programs by medically underserved and minorities (for example, African–Americans, Latino–Americans, Asian–Americans), and other population groups that have historically been under-represented in the provision of cardiac catheterization services (for example, Medicaid recipients, indigent/self-pay patients), will be achieved. This plan is subject to review and approval by the Department and will be based on the extent that cardiac catheterization services will be provided to these population groups in comparison to inpatient admission rates for acute myocardial infarction or other access criteria developed by the Department of Health and Senior Services by these same population groups in the proposed area.

3. All hospitals shall document in their application 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.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (a)1 and 2, substituted "in the pilot", for "low risk" and in (a)2, substituted "facility" for "program".

8:33E–1.8 Agreements for cardiac surgery services

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter which is not also licensed to provide cardiac surgery services on site shall develop and maintain written agreements with cardiac surgery centers which shall include, but not necessarily be limited to: provisions for insuring quality control, rapid referral for surgery, emergency backup and transport procedures, and regular communication between the cardiologist performing catheterization and the surgeons to whom patients are referred. In addition, one of the referral agreements must be within one hour travel time from the diagnostic facility and at least one of the referral agreements shall be written with a New Jersey cardiac center.

(b) To insure that costs are not unnecessarily increased by duplication of procedures, written assurance shall be included within the referral agreement stating that, to the greatest extent possible, the receiving facility will accept the results of the diagnostic facility's examinations. Departures from this practice shall be limited to an established peer review mechanism at the receiving center.

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 "and transport" preceding "procedures".

8:33E–1.9 Data reporting

(a) Every facility licensed to provide invasive cardiac diagnostic services in accordance with this subchapter shall maintain and provide statistical patient level data on the operation of the program and report those data to the Department of Health and Senior Services on a quarterly basis and in a standardized format determined by the Department. These cumulative patient level data will be submitted to the Department of Health and Senior Services on a quarterly basis, within 30 days after the close of the quarter. 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.

1. In addition to the reporting requirements of paragraph (a) above, statistical data submitted by all facilities licensed to provide low risk invasive cardiac diagnostic services pursuant to the low risk catheterization facility described in this subchapter must, prior to submission to the Department, be audited and verified by an independent auditing body approved by the Department. Each low risk catheterization facility will be responsible for the entire cost of its own audits and shall provide the Department with any and all documentation substantiating the findings of the auditor for compliance with utilization and quality standards at N.J.A.C. 8:33E–1.4 and 1.6. This independent auditing requirement shall apply only to low risk catheterization facilities.

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), deleted "as set forth in this subchapter" following "patient level data" and in (a)1, substituted "low risk" for "pilot" and "facilities" for "programs".

8:33E–1.10 Certification of nondiscriminatory practices

Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter shall provide the Department with, and shall maintain current, a written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients as those laws may be amended from time to time.

8:33E–1.11 Requirements for submission of certificate of need applications to initiate invasive cardiac diagnostic services other than low risk catheterization facilities

(a) Applications to initiate full service invasive adult cardiac diagnostic services will only be accepted by the Department in accordance with the eligibility and application review criteria set forth at N.J.A.C. 8:33E–1.15. All such applications will be subject to the expedited certificate of need review process set forth at N.J.A.C. 8:33–5.

(b) All applications to initiate full service invasive cardiac diagnostic services shall include documentation of compliance with the applicable standards and criteria of this subchapter, specifically those set forth at N.J.A.C. 8:33E–1.3 through 1.10. Failure to include such documentation will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

(c) Except where specifically exempted or superseded, the requirements for submission of certificate of need applications to initiate full service invasive cardiac diagnostic services as set forth in (a) through (b) above, shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. 26:2H–1 et seq.; N.J.A.C. 8:33; and 8:43G.

(d) All applicants for any full service invasive cardiac diagnostic services, must, through a resolution of their Board of Directors, acknowledge and accept the standards and criteria set forth in this subchapter as conditions of approval and licensure. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Deleted references to expansion of invasive cardiac diagnostic services throughout; deleted former (d); and recodified former (e) and (f) as (d) and (e).
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–1.12 Requirements for submission of certificate of need applications to provide low risk invasive cardiac diagnostic services as a low risk catheterization facility.

(a) Applications to initiate low risk invasive cardiac diagnostic services will only be accepted in response to a one-time call for such services to be issued at the discretion of the Commissioner. All such applications will be processed on an expedited review basis pursuant to N.J.A.C. 8:33–5.

(b) All applications to initiate low risk invasive cardiac diagnostic services shall include full written documentation of the projected implementation and operational costs of the proposed program. This documentation shall 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. Projection of anticipated revenues shall be supplied for at least the first three years. Failure to include such documentation will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

(c) All applications to initiate low risk invasive cardiac diagnostic services pursuant to the low risk catheterization facility described in this subchapter shall also include documentation of compliance with the applicable standards and criteria of this subchapter specifically those set forth at N.J.A.C. 8:33E–1.3 through 1.10. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

(d) Except where specifically exempted or superseded, all applications to initiate low risk invasive cardiac diagnostic services shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. 26:24–1 et seq.; N.J.A.C. 8:33; and N.J.A.C. 8:43G.

(e) All applicants, through a resolution of its Board of Directors, shall acknowledge and accept the standards and criteria set forth herein as conditions of approval and agree to be bound by all provisions of this chapter, and particularly with respect to the licensure requirements in N.J.A.C. 8:33E–1.13. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

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–1.13 Requirements for licensure of certificate of need approved invasive cardiac diagnostic facilities

(a) All facilities seeking to initiate invasive cardiac diagnostic services pursuant to an approved certificate of need shall be initially licensed on an annual basis in accordance with the provisions of N.J.A.C. 8:43G.

(b) Licenses for facilities referenced in (a) above may be renewed on an annual basis only upon a demonstration by the license holder to the satisfaction of the Commissioner, of full compliance with all applicable standards and criteria of this chapter, N.J.A.C. 8:43G; N.J.A.C. 8:33; N.J.S.A. 26:2H–1 et seq.; any applicable Federal law; and any additional conditions imposed upon the license holder in the original certificate of need approval.

1. All facilities seeking renewal of licenses issued pursuant to the full service or low risk cardiac catheterization facility described in this subchapter shall submit to the Department of Health and Senior Services, documentation of their full compliance with all standards and criteria referenced in (b) above, specifically including, but not limited to, the verified utilization criteria pursuant to N.J.A.C. 8:33E–1.4(b) and 1.9 for full service cardiac catheterization facilities and independently audited and verified utilization criteria pursuant to N.J.A.C. 8:33E–1.4(c) and 1.9(a)1 for low risk cardiac catheterization facilities. Where applicable, plans of correction shall be submitted indicating what licensure renewal criteria are deficient, what corrective actions are to be put in place or what systemic changes shall be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance.

i. Failure to submit all information/documentation and corrective actions required for consideration of renewal in the time and manner set forth in (b) above shall, absent the express written consent of the Department, constitute a basis for denial of the request for license renewal.

(c) Upon receipt of the documentation required for renewal as set forth in (b) and (b)1 above, the Department shall review and evaluate the documentation, shall communicate with the facility to clarify and/or supplement the documentation as it in its sole discretion deems appropriate, and shall communicate in a timely manner a decision to the facility as to whether the license to provide full service or low risk cardiac catheterization services, whichever is applicable, will be renewed.

(d) Any renewal of licensure under this section shall be valid for a period of one year only and shall be limited to the same invasive cardiac diagnostic services as were approved under the license holder's original certificate of need and initial license. Failure of an existing cardiac catheterization provider to document compliance with annual licensure renewal criteria will require the provider 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 standard in N.J.A.C. 8:33E–1.4(b)1 or (c)1 and physician volume standard in N.J.A.C. 8:33E–1.4(b)2 or (c)2, whichever are applicable. Where applicable, plans of correction shall be submitted indicating what licensure renewal criteria are deficient, what corrective actions are to be put in place or what systemic changes 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 shall 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;

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.

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

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote (b); added new (c) and (d); recodified former (c) as (e).

8:33E–1.14 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. At the request of the Commissioner, this 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.

Recodified from N.J.A.C. 8:33E–1.15 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 section. Former N.J.A.C. 8:43E–1.14, Requirements for licensure of certificate of need approved for low risk invasive cardiac diagnostic "pilot catheterization programs", repealed.

8:33E–1.15 Requirements for submission of certificate of need applications to provide full service invasive cardiac diagnostic services

(a) Applications to provide new full service invasive cardiac diagnostic services pursuant to the requirements in this subchapter shall be accepted on a semi-annual basis, with all such applications to be submitted on the first business day of January and July of each year. Such applications shall be processed on an expedited review basis pursuant to N.J.A.C. 8:33–5.1(b)2. Eligibility for the submission of such applications shall be limited to the following:

1. Licensed providers of low risk cardiac catheterization services that have demonstrated full unconditional compliance with State licensure requirements that includes, but is not limited to, compliance with the minimum annual facility volume requirement for full service cardiac catheterization (that is, 500 cases) as set forth at N.J.A.C. 8:33E–1.4(b)1 throughout 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. Failure to include such documentation shall result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

(b) All applications to convert low risk invasive cardiac diagnostic services pursuant to the requirements described in this subchapter shall also include documentation of compliance with the applicable standards and criteria of this subchapter, specifically those set forth at N.J.A.C. 8:33E–1.3 through 1.13. Failure to include such documentation at the time of filing will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33–4.5.

(c) Except where specifically exempted or superseded, all applications to convert low risk invasive cardiac diagnostic services pursuant to the criteria described in this subchapter shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. 26:24–1 et seq.; N.J.A.C. 8:33; and N.J.A.C. 8:43G.

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–1.15, Commissioner's cardiovascular health advisory panel (CHAP), recodified to N.J.A.C. 8:33E–1.14.

SUBCHAPTER 2. REGIONAL CARDIAC SURGERY CENTERS

8:33E–2.1 Scope and purpose

(a) The purpose of this subchapter is to establish standards and general criteria for the planning of a regional cardiac surgical center and for the preparation of an application for a certificate of need for such a facility. A regional approach to the provision of cardiac services is necessary to provide safe, complete patient care, efficiently and effectively, at reasonable cost to the consumer. Cardiac surgery centers provide the full-range of diagnostic, therapeutic and surgical cardiac services.

(b) A regional cardiac surgical center is defined as a health care facility which specializes in most aspects of cardiac service, including at a minimum cardiovascular surgical services as well as invasive cardiac diagnostic and therapeutic catheterization (for example, PTCA, complex EPS) services. With the exception of an inner city cardiac satellite demonstration project as specified at N.J.A.C. 8:33–3.11(c), these cardiac surgery services are to be provided at a single hospital location.

(c) In the regional cardiac surgical center, the primary diagnostic services are provided by a cardiac catheterization and coronary angiographic laboratory and a non-invasive laboratory. A cardiac catheterization, coronary angiographic laboratory is one which provides a service devoted to achieving physiological and angiographic studies of optimal quality. Application for certificate of need approval to provide and/or the provision of invasive cardiac diagnostic services by a regional cardiac surgery center shall be subject to all applicable standards and criteria for such services as set forth at N.J.A.C. 8:33E.

(d) At a minimum, the non-invasive laboratory shall include the following facilities:

1. ECG instruments;
2. Exercise Stress testing;
3. Echocardiography equipment;
4. Holter-type monitoring; and
5. Nuclear cardiology.

(e) Before heart surgery is performed, every patient shall undergo diagnosis through a recognized diagnostic service, except in an extreme emergency, as in the case of open wounds to the heart.

(f) The cardiovascular surgical services include open heart, closed heart and coronary artery surgery, as well as surgery of the great vessels, and cardiac assist devices, such as the intra-aortic balloon pump. Therapeutic catheterization procedures include PTCA or balloon angioplasty. The requirements contained in this subchapter for facilities, personnel and equipment for open heart surgery shall be the minimum requirements for all cardiovascular surgical and interventional cardiology procedures.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote (b) and (f).
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (b), inserted "and therapeutic catheterization (for example, PTCA, complex EPS)" following "diagnostic"; rewrote (f).

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.

Commissioner of Health's conclusory determinations, that certificate of need for cardiac surgery facility would make cardiac services more accessible to area residents, would not reduce quality of patient care in region, and that applicant would have enough cardiac cases to meet minimum utilization requirements, were not sufficient to show that application was properly granted. In re Valley Hosp., 240 N.J.Super. 301, 573 A.2d 203 (A.D.1990), certification denied 126 N.J. 318, 598 A.2d 879.

8:33E–2.2 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 invasive therapeutic cardiac services 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 higher 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.

"Hospital system" means a group of licensed acute care hospital facilities owned or controlled by the same legal entity.

"Inner city cardiac satellite demonstration project" means a cooperative expansion of invasive therapeutic cardiac services within a hospital system, whereby a satellite hospital within the system is permitted to provide invasive therapeutic cardiac services already provided by an inner city hospital within the same hospital system and which meets all of the criteria set forth in this chapter and N.J.A.C. 8:33.

"Inner city hospital" means an acute care hospital which is located in a city with a population greater than 50,000 (or in a city with a population greater than 10,000 located in a county of population density greater than 2,500 persons per square mile) and in which more than 10 percent of families in the city have income levels which are below the Federal poverty line, as determined in accordance with 42 U.S.C. § 9902(2).

"Invasive therapeutic cardiac services" means the full array of therapeutic cardiac interventional procedures that includes, but is not limited to, coronary artery bypass graft (CABG) surgery, percutaneous transluminal coronary angioplasty (PTCA), and complex electrophysiology studies (EPS).

"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 patients" shall be as 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.

"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 must 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.

"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 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. Elective PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent) PTCA procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E–2.16.

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.
Amended by R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Rewrote (d)3.

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 Regional responsibilities of cardiac surgery centers

(a) Each cardiac surgery center shall have written transfer agreements to receive appropriate cardiac patients from hospitals located in the same county as the cardiac surgery center or a contiguous county. Additional transfer agreements with hospitals outside the county or a contiguous county are not prohibited. The transfer agreements shall include, but not be limited to, provisions establishing the following:

1. Provision by the cardiac surgery center of specifically identified contacts available 24 hours per day, seven days per week who are authorized to make an immediate decision regarding the cardiac surgery center's ability to accept transfer of a patient;

2. The responsibilities of each facility in assuring that appropriately equipped transport vehicles with trained nursing support during transport is available as needed for patient transfer 24 hours per day, seven days per week;

3. Provision by the cardiac surgery center of an ongoing educational program for physicians, nurses and unlicensed assistive personnel relating to topics including, but not limited to, recognition of symptoms of cardiac distress and diagnosis of cardiac conditions;

4. Provision by the cardiac surgery center of training in therapies, such as insertion of an intra-aortic balloon pump, required to stabilize patients for transfer, and the responsibilities of each facility in assuring that therapies to stabilize patients for transfer are available 24 hours per day, seven days per week; and

5. Availability through the cardiac surgery center of consultation 24 hours per day, seven days per week to assist in the diagnosis of patients presenting at the other facility with possible cardiac symptoms.

(b) Each applicant shall agree to send out a mailing to all appropriate institutions and physicians stating that the services of the center are available, including as appropriate, the training, back-up and consultation services addressed in the transfer agreements. Following certificate of need approval, the cardiac surgery center shall provide the Department with written documentation that this mailing has occurred.

(c) 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 facility. The institutional policy statement shall govern all cardiac services, be reviewed annually, and be revised as needed.

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 "Referral".

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 Petition for and submission of certificate of need applications

(a) All certificate of need applicants 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 in this section and in N.J.A.C. 8:33. Certificate of need applications shall only be accepted for processing from general hospitals after a hospital has petitioned the Department and established the potential need for new cardiac surgery services by demonstrating that it meets the following minimum standards, which indicate a potential unmet need and that the petitioner is qualified to meet the unmet need:

i. The petitioner is an existing provider of full service invasive cardiac diagnostic services that has complied with all applicable requirements at N.J.A.C. 8:43G–7 and in this chapter and has for the previous three years met or exceeded the minimum acceptable number of adult cardiac catheterization cases required for a full service cardiac laboratory in accordance with N.J.A.C. 8:33E–1.4(b)1 as demonstrated by the most current data maintained by the Department;

ii. The petitioner is not located in the same county as a facility which, in the previous 12 months, successfully petitioned the Department for a call;

iii. The petitioner can demonstrate a potential volume of at least 350 cardiac surgery cases per year, based on one or more of the following. In demonstrating this potential volume, petitioners must provide a detailed explanation of the methodology used to identify potential cases based on minority, medically underserved and/or out-of-State residents and the Department shall indicate whether it accepts the number of cases identified through this methodology. The Department shall, on an annual basis, indicate what proportion of the 350 cases shall be derived from each of the specific criteria listed below:

(1) Patients receiving diagnostic cardiac catheterizations at the petitioner's facility who had cardiac surgery within the following 90 days;

(2) People residing in the county where the petitioner is located who had cardiac surgery in the previous year at a facility outside the petitioner's service area, which shall include the petitioner's county and contiguous counties, including at out-of-State facilities;

(3) Potential cases from minority and/or medically underserved patients in the petitioner's county or in a contiguous county; and/or

(4) Potential cases from out-of-State residents;

iv. The petitioner can demonstrate that retaining cardiac surgery cases that currently are referred to an existing New Jersey cardiac surgery center(s) is not likely to cause cardiac surgery volume at that facility(ies) to fall below the minimum annual volume required for maintenance of quality and is consistent with the findings of the Legislature as set forth at N.J.S.A. 26:2H–6.1(h); and

v. The petitioner can demonstrate the current availability, and quantify the utilization of, its cardiology and/or cardiovascular disease community prevention services and clinics for all populations, specifically targeting minority and medically underserved population groups. Examples of community prevention programs are those primary and secondary prevention initiatives which include:

(1) Diet and drug therapy for hypercholesterolemia in patients at high risk or with established coronary artery disease;

(2) Smoking cessation programs with objective outcome measures;

(3) Exercise rehabilitation programs for patients with established coronary artery disease; and

(4) Public education programs.

2. The petition review process shall include four review cycles each year. The beginning of each cycle shall be the first business day of January, April, July and October. Petitions shall be accepted on the first business day of each cycle. A decision shall be rendered by the Commissioner no later than 90 days after the beginning of the cycle in which a petition is received as to whether the petitioner has met the minimum standards necessary for the Department to initiate a regional call for submission of certificate of need applications for a new cardiac surgery program. The petitioner shall submit a nonrefundable fee of $5,000 to the Department along with the petition. If the Department makes a finding of potential need and issues a regional call for cardiac surgery certificate of need applications, the petitioner may apply this fee toward the certificate of need application fee.

3. In the event the petitioner is unsuccessful in establishing the potential need for new cardiac surgery services, the Department shall not accept a petition for cardiac surgery services from that petitioner for two years subsequent to the date the unsuccessful petition was submitted to the Department for consideration. An unsuccessful petition, however, does not preclude the petitioner from submitting an application in response to any call resulting from the action of another petitioner and applying to the county in which the applicant whose own petition was denied is located.

4. Within 60 days of the Commissioner's determination that a petitioner has met the minimum standards necessary to issue a regional call for submission of certificate of need applications for a new cardiac surgery program, the Commissioner shall publish a call. The call shall invite cardiac surgery applications from any general hospital, including petitioner, located in the petitioner's county or a contiguous county that meets the criteria set forth in (a)1i above. It will also invite existing New Jersey cardiac surgery centers located in the petitioner's county or a contiguous county ("affected facilities") to file a written submission with the Department in response to any submitted certificate of need applications that have been deemed complete. The published call shall set forth time frames for the submission of applications, the determination of completeness of the 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).

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 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".

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

(a) The Department's goal in considering applications for provision of PTCA without the availability of on-site cardiac surgery in emergent situations is to promote wider access to appropriate emergency PTCA 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 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 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 PTCA 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 PTCA 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 PTCA cases per year. The applicant is able to document that it will maintain this minimum volume in subsequent years. Primary PTCA 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 PTCA will be available 24 hours/day, seven days per week;

6. The applicant is able to document that each operator performing primary PTCA is an experienced interventionalist who performed at least 75 PTCA cases at a cardiac surgery center in the previous year and continues to do so during his or her tenure at the free-standing PTCA 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 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 8:43G–7.29 and 7.30;

10. The applicant is able to document its ability to perform primary PTCA 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 PTCA 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 PTCA services, the Department will:

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

(e) Facilities granted a certificate of need to provide primary PTCA in emergent situations without on-site cardiac surgery shall 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 shall 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".