CHAPTER 33E

CERTIFICATE OF NEED: CARDIAC DIAGNOSTIC FACILITIES AND CARDIAC SURGERY CENTERS

Authority

N.J.S.A. 26H–1 et seq., specifically 26:2H–5 and 2H–7.

Source and Effective Date

R.1996 d.104, effective February 20, 1996.
See: 27 N.J.R. 3895(b), 28 N.J.R. 1252(a).

Executive Order No.66(1978) Expiration Date

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, expires on February 20, 2001.

Chapter Historical Note

Chapter 33E, "Certificate of Need: Cardiac Facilities" became effective May 23, 1977 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). The appendix originally contained rules concerning "Basic Statistical Data required for Each Diagnostic Facility—Inventory of Catheterization—Angiographic Laboratories (Number of Diagnostic Examinations)". Amendments to Subchapter 1 became effective July 20, 1979 as R.1979 d.286. See: 11 N.J.R. 278(a), 11 N.J.R. 439(a). Amendments to Subchapter 2 became effective July 20, 1979 as R.1979 d.289. See: 11 N.J.R. 278(b), 11 N.J.R. 440(a). Chapter 33E was originally codified as N.J.A.C. 8:11, and was recodified on September 13, 1979 as N.J.A.C. 8:33E. Amendments became effective February 1, 1982 as R.1982 d.24. See: 13 N.J.R. 649(a), 14 N.J.R. 147(d). Amendments became effective February 1, 1982 as R.1982 d.25. See: 13 N.J.R. 651(a), 14 N.J.R. 147(e). Appendix A was repealed by R.1982 d.24. (See above.) Amendments became effective August 6, 1984 as R.1984 d.325. See: 16 N.J.R. 1154(a), 16 N.J.R. 2122(a). Subchapter 2 expired July 19, 1984 pursuant to Executive Order No. 66(1978). Chapter 33E was readopted with amendments effective July 20, 1987 as R.1987 d.296. See: 19 N.J.R. 606(a), 19 N.J.R. 610(c), 19 N.J.R. 1304(a), 19 N.J.R. 1307(a). Amendments became effective July 19, 1988 as R.1988 d.320 and d.321. See: 20 N.J.R. 467(a), 20 N.J.R. 468(a), 20 N.J.R. 1690(b). Amendments became effective February 21, 1989 as R.1989 d.102. See: 20 N.J.R. 2847(a), 21 N.J.R. 498(a). Chapter 33E, Surgical Facilities, expired on June 23, 1992, pursuant to Executive Order No. 66(1978). 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). Chapter 33E expired on December 20, 1995, pursuant to Executive Order No. 66 (1978).

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: Source and Effective Date.

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SUBCHAPTER 1. INVASIVE 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 collocated, the invasive cardiac diagnostic facility does not provide cardiac surgery 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. A regional approach to the provision of invasive cardiac diagnostic services provides safe, complete patient care, efficiently and effectively, at reasonable cost to the consumer. To increase access to these services, and as a supplement to the existing network of cardiac diagnostic facilities N.J.A.C. 8:33E–1.12 establishes a pilot program that permits additional new low risk cardiac catheterization programs under a limited approval basis that is

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, complete patient care, efficiently and effectively at reasonable cost to the consumer.

1. As of February 20, 1996, there will be a new category of invasive cardiac diagnostic catheterization facility that will 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 a new pilot program proposed at N.J.A.C. 8:33E–1.12. If approved, the services must be fully implemented within 12 months from the time the certificate is granted.

(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. The non-invasive laboratory is commonly available at all acute care hospitals and is devoted to non-invasive cardiac testing which may include, at a minimum, ECG instruments, exercise stress testing, Doppler technology/ echocardiography equipment and Holter type monitoring and nuclear cardiology (often in a separate department) 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 maximum utilization of the State's existing 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. Therefore, 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.

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 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.

4. 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 pediatric experience for pediatric cardiac surgery centers.

5. 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.

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

7. 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 video tape and be responsible for the care and maintenance of all radiologic equipment.

8. 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.

9. 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.

8:33–1.6 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.

(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 pilot cardiac catheterization program shall also provide written documentation that the proposed service 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 for review and approval;

2. A physician-specific and overall pilot 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 pilot laboratory reporting more than a 50 percent increase in the number of normal studies during any 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 pilot 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 pilot catheterization program will be monitored by the Department. In doing so, the Department will seek the assistance of the Cardiovascular Health Advisory Panel; and

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

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 in the pilot catheterization program, 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 in the pilot catheterization program, 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. The 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 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.

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 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.

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 as set forth in this subchapter on the operation of the program and report those data to the Department of Health 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 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, Division of Health Care Systems Analysis, Research and Development Program, Room 600 CN 360, Trenton, New Jersey 08625.

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 pilot catheterization program 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 pilot catheterization program 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 pilot catheterization 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 or expand invasive cardiac diagnostic services other than pilot catheterization programs

(a) Applications to initiate or expand invasive cardiac diagnostic services will only be accepted by the Department in response to a call for such services which may be issued at the discretion of the Commissioner. All such applications will be subject to the full certificate of need review process set forth at N.J.A.C. 8:33–4.

(b) All applications to initiate or expand 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. Projections of anticipated revenues shall be supplied for at least the first three years.

(c) All applications to initiate or expand 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. 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.

(d) In addition to the requirements set forth in (a), (b) and (c) above, and except as provided for pilot program expansions in N.J.A.C. 8:33E–1.12(d), applications seeking to expand existing invasive cardiac diagnostic services shall include documentation of compliance with N.J.A.C. 8:33E–1.4(a) and (b) and the following:

1. The Department of Health will only process certificate of need applications for the expansion of existing invasive cardiac diagnostic facilities located in local advisory board areas, designated pursuant to the New Jersey Health Care Facilities Planning Act (P.L. 1971, c.136 and 138) and amendments thereto, and in accordance with procedures set forth below and in N.J.A.C. 8:33. Certificate of need applications will only be accepted for processing from existing cardiac catheterization providers located in local advisory board areas where all existing invasive cardiac diagnostic facilities and services meet minimum levels of utilization, per laboratory, as specified at N.J.A.C. 8:33E–1.3(b) and where the applicant's level of utilization during the most recent calendar year prior to submission of the application exceeds 1,800 diagnostic catheterization procedures per laboratory for facilities without cardiac surgery on site and 2,500 cardiac catheterization equivalents per laboratory for facilities located within an adult cardiac surgery center. Documentation shall be provided that indicates that other existing area providers of this invasive cardiac diagnostic service will not be jeopardized by the proposed new service.

(e) Except where specifically exempted or superseded, the requirements for submission of certificate of need applications to initiate or expand invasive cardiac diagnostic services as set forth in (a) through (d) 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 N.J.A.C. 8:43.

(f) All applicants for any 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.

8:33E–1.12 Requirements for submission of certificate of need applications to provide low risk invasive cardiac diagnostic services as a pilot catheterization program

(a) Applications to initiate or expand low risk invasive cardiac diagnostic services pursuant to the pilot catheterization program described in this subchapter 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 or expand low risk invasive cardiac diagnostic services pursuant to the pilot catheterization program described in this subchapter 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. Projections 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 or expand low risk invasive cardiac diagnostic services pursuant to the pilot catheterization program 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) In addition to the requirements set forth in (a), (b) and (c) above, applications seeking to expand existing invasive cardiac diagnostic services as a pilot catheterization program shall include documentation of compliance with N.J.A.C. 8:33E–1.4(c) and the following:

1. Hospitals submitting certificate of need applications to establish a pilot catheterization program shall be limited to a single laboratory. These pilot programs, which shall undergo an expedited review in accordance with the Certificate of Need Policy Manual at N.J.A.C. 8:33–1.5(a)18, shall be exempt from the limitation of one certificate of need approval per local advisory board cited in subsection N.J.A.C. 8:33E–1.11(d)2.

2. Applicants documenting compliance with all requirements contained in this subchapter to participate in a pilot catheterization program facility will be approved for a period not to exceed 30 months from the initiation of services. Approved applicants shall have one year from the date of this approval in which to implement the program and be licensed. If licensure has not occurred within one year, the certificate of need approval will not be extended by the Department of Health. At the conclusion of this 30 month pilot study period, each applicant will be evaluated by the Department with regard to compliance with the pilot study criteria contained herein in accordance with the procedures for license renewal set forth at N.J.A.C. 8:33E–1.14. In accordance with N.J.A.C. 8:33–4.16(b), pilot laboratory sites approved under this cardiac pilot study will be subject to a condition of approval permitting the Commissioner to nullify the certificate of need and not issue a license renewal to continue to provide the service. As a condition of approval, in the event that license renewal is not granted pursuant to the licensing renewal criteria contained in this subchapter, the unlicensed service will be suspended pending the outcome of all administrative hearings and appeals.

(e) Except where specifically exempted or superseded, all applications to initiate or expand low risk invasive cardiac diagnostic services pursuant to the pilot catheterization program 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. 8:33–1; and N.J.A.C. 8:43.

(f) 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–1.14. 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.

8:33E–1.13 Requirements for licensure of certificate of need approved invasive cardiac diagnostic facilities other than pilot catheterization programs

(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. 8:43B; 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.

(c) 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.

8:33E–1.14 Requirements for licensure of certificate of need approved facilities for low risk invasive cardiac diagnostic "pilot catheterization programs"

(a) All facilities seeking to initiate low risk invasive cardiac diagnostic services pursuant to an approved certificate of need issued in accordance with the pilot catheterization program described in this subchapter shall be initially licensed in accordance with the provisions of N.J.A.C. 8:43G except as specifically set forth below.

1. Initial licenses granted to pilot catheterization program facilities shall be valid for a period not to exceed 30 months from the month in which the facility initiates low risk invasive cardiac diagnostic services under the pilot catheterization program.

i. As set forth at N.J.A.C. 8:33E–1.12(d)2, facilities with approved certificates of need to provide low risk invasive cardiac diagnostic services under the pilot program shall have one year from the date of the certificate of need approval letter to initiate such services.

2. Initial licenses granted to pilot catheterization program facilities shall expire automatically without the need for further notification or other action by the Department of Health, at the end of the 30th month following the month in which the facility initiates low risk invasive cardiac diagnostic services under the pilot catheterization program.

(b) Following the expiration of the initial license, licenses for pilot catheterization programs to provide low risk invasive cardiac diagnostic services may be renewed 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 for low risk invasive cardiac diagnostic pilot catheterization programs, 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, and only in accordance with the following protocol:

1. No earlier than the completion of the 24th month following the initiation of invasive cardiac diagnostic services under the pilot catheterization program, and no later than the completion of the 26th month following the initiation of such services, all facilities seeking renewal of licenses issued pursuant to the pilot program described in this subchapter shall submit to the Department of Health, documentation of their full compliance with all standards and criteria referenced in (b) above, specifically including, but not limited to, the independently audited and verified utilization criteria pursuant to N.J.A.C. 8:33E–1.4(c) and 1.9.

i. Failure to submit all information/documentation required for consideration of renewal in the time and manner set forth in paragraph (b)1 above shall, absent the express written consent of the Department, constitute a basis for denial of the request for license renewal.

ii. Following the completion of the 26th month after the initiation of services under the pilot catheterization program described in the subchapter, documentation of compliance with the requirements of paragraphs (b) and (b)1 above, shall only be accepted for consideration at the express written request of the Department.

(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, no later than the completion of the 30th month following the month in which the facility initiated services under the pilot catheterization program, communicate a decision to the facility as to whether the license to provide services approved under this pilot catheterization program will be renewed.

(d) Facilities not receiving an express written notification of the renewal of their license to provide low risk invasive cardiac diagnostic services authorized under the pilot catheterization program described in this subchapter in accordance with (c) above, shall cease all such services as of the completion of the 30th month following the month in which such services were initiated and make medically appropriate referrals for all patients.

(e) Any renewal of licensure under this section shall be valid for a period of one year only and shall be limited to the same low risk invasive cardiac diagnostic services as were approved under the license holder's original certificate of need and initial license.

(f) Licenses renewed in accordance with the provisions of this section shall thereafter be eligible for renewal 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 for low risk invasive cardiac diagnostic pilot catheterization programs; N.J.A.C. 8:43G; N.J.A.C. 8:33; N.J.S.A. 26:2A–1 et seq.; any applicable Federal law; and any additional conditions imposed upon the license holder in the original certificate of need approval.

(g) The requirements for licensure in this section 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.

8:33E–1.15 Commissioner's cardiovascular health advisory panel (CHAP)

(a) A cardiovascular health advisory panel has been established, under the authority of the Commissioner of Health, to participate in the development of 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 the degree to which these developments have achieved clinical acceptance within the medical community;

3. Review State standards and criteria for cardiac services and Statewide cardiac service performance; and

4. Respond to Statewide issues regarding cardiac care; and

5. Assist in the development and implementation of Statewide cardiac research and data activities.

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 services. 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 also cardiac assist devices, such as the intra-aortic balloon pump. The requirements contained in this subchapter for facilities, personnel and equipment for open heart surgery shall be the minimum requirements for all cardiovascular surgical procedures.

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 treatment modalities including open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG) surgery, PTCA and 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.

"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 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 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 pilot 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).

"Open heart surgery" refers to a procedure 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) 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.

"Pilot catheterization program" 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 myocardiac 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.

8:33E–2.3 Utilization of cardiac surgical centers

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

1. Once criteria for new cardiac surgery services are developed at N.J.A.C. 8:33E–2.13 below, utilization criteria and standards for new cardiac surgery services will be specified and promulgated at that time.

2. All existing regional adult cardiac surgical centers shall continue to perform at least 250 open heart surgical procedures per year per operating room to insure the competency of the surgical services team and to provide for efficient and economical operation.

3. Existing regional adult cardiac surgery centers shall document a volume of 350 open heart surgical procedures per year per operating room in order to be considered for an expansion of its operating room capacity.

4. Existing regional adult cardiac surgery centers that are in compliance with all minimum standards and criteria contained in this subchapter, including the minimum volume requirements for percutaneous transluminal coronary angioplasty (PTCA) at (d) below, may utilize a separate operating room for PTCA backup. This backup operating room shall not be utilized for routine cardiac surgery and shall not be considered a cardiac operating room for purposes of this subchapter.

5. Each cardiac surgical center shall establish a minimum caseload per physician and team in order to ensure a consistent level of proficiency within the surgical program. As recommended in the Commissioner's Cardiac Services Task Force (CSTF) report, a minimum of 100 cases per year shall be maintained to preserve the professional skills of a supervising cardiac surgeon, which shall refer to the physician in charge of the specific case.

(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. As

recommended by the Commissioner's Cardiac Services Task Force (CSTF), 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 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)–(e), 2.4(d)–(f), 2.10 and 2.15, the provision of adult 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.

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 within this one year of the effective date of this subchapter and shall maintain this standard on an annual basis thereafter.

3. PTCA procedures must be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

4. Each PTCA facility shall establish a minimum number of PTCA procedures for each physician with PTCA laboratory privileges. As recommended by the Commissioner's Cardiac Services Task Force (CSTF), each physician seeking to continue to perform 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), and 50 PTCA cases per year, as primary physician, to preserve a consistent level of proficiency.

(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 service implementation.

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 within one year of the effective date of this subchapter and shall maintain this standard on an annual basis thereafter.

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. As recommended by the Commissioner's Cardiac Services Task Force (CSTF), 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.

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. Based on 250 open heart procedures the basic team of the regional cardiac surgical center for each operation shall consist of the following permanently assigned staff:

i. One physician in charge, board-certified by the American Board of Thoracic and Cardiovascular Surgery as a cardiovascular surgeon who directs the team or the surgical unit. Based on the Commissioner's Cardiac Task Force recommendation, the physician in charge must perform a minimum of 100 procedures annually;

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

ii. One assistant to the physician in charge 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) 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 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–1.4.

2. Exceptions to these minimum training and certification requirements for incumbent directors and associate physicians may be granted by the Commissioner after consultation with the CHAP 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 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 minimally 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 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.

8:33E–2.5 Use of inpatient facilities

(a) In a center performing 250 open heart surgical procedures 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).

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, to participate in the development of cardiovascular health policy. This committee shall also:

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

2. Review cardiac service technological developments and the degree to which these developments have achieved clinical acceptance within the medical community;

3. Review State standards and criteria for cardiac services and Statewide cardiac service performance;

4. Respond to Statewide issues regarding cardiac care, as requested by the Commissioner of Health;

5. Assist in the development and implementation of Statewide cardiac research and data activities.

8:33E–2.7 Referral

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

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

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

8:33E–2.8 (Reserved)

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

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

8:33E–2.10 Statistical data required

(a) Every cardiac facility licensed to provide therapeutic interventional cardiac procedures that include, but are not limited to, cardiac surgery and coronary angioplasty services in accordance with this subchapter shall maintain and provide statistical patient level data as set forth in this subchapter on the operation of the program and report those data to the Department of Health on a quarterly basis and in a standardized format determined by the Department. These cumulative patient level data shall be submitted to the Department of Health 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, Division of Health Care Systems Analysis, Research and Development Program, Room 600 CN 360, Trenton, New Jersey 08625.

(b) In accordance with N.J.A.C. 8:33E–2.13, regional cardiac surgery centers applying to provide or providing low risk invasive cardiac diagnostic services as pilot catheterization programs shall also be subject to the maintenance and reporting of data requirements of N.J.A.C. 8:33E–1.9.

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 Peer review

(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 diagnostic facility. 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 as recommended by the Cardiac Service Task Force 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 firms, number of restudies performed elsewhere);

(b) In all cases, criteria selection should be based on sound medical practice and consistency with the literature. Cardiac surgical centers with marginal utilization (10 percent above or below minimum utilization standards) will be reviewed by the CHAP to assure appropriate case selection has occurred.

8:33E–2.13 New facilities; diagnostic pilot cardiac catheterization programs at cardiac surgery centers

Except as specifically set forth in this subchapter, all regional cardiac surgery centers applying to provide or providing invasive cardiac diagnostic services pursuant to the pilot program described in N.J.A.C. 8:33E–1, Invasive cardiac diagnostic facilities, shall be subject to all applicable standards and criteria for such services as set forth at N.J.A.C. 8:33E–1.

8:33E–2.14 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. Existing providers failing to achieve minimum utilization standards specified in this subchapter within one year following the effective date of this subchapter and each year thereafter will be subject to reimbursement or licensing sanctions. These sanctions may include closure of the service or that portion of the service that will result in compliance with minimum State standards.

(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 within three years from the initiation of the service. Failure to achieve the minimum level by the end of the second year of operation will result in notification of Department of Health intention to rescind certificate of need approval and more for licensing sanctions. The inability to achieve minimum utilization levels during the third year of operation or thereafter will result in loss of license for the service.

8:33E–2.15 Submission of Certificate of Need applications

In accordance with N.J.A.C. 8:33E–2.1(c) and 2.13, all certificate of need applications by regional cardiac surgery centers for invasive cardiac diagnostic services shall be subject to the applicable requirements of N.J.A.C. 8:33E–1.11 and 1.12.