CHAPTER 33E

CERTIFICATE OF NEED: CARDIAC DIAGNOSTIC FACILITIES AND CARDIAC SURGERY CENTERS

Authority

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

Source and Effective Date

R.1993 d.670, effective December 20, 1993.
See: 25 N.J.R. 3712(a), 25 N.J.R. 6019(b).

Executive Order No. 66(1978) Expiration Date

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, expires on December 20, 1995.

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). This chapter was originally codified as N.J.A.C. 8:11; it 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 Appendix A was repealed by R.1982 d.24.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). This chapter 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. See: Source and Effective Date.

See section annotations for specific rulemaking activity.

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SUBCHAPTER 1. INVASIVE CARDIAC DIAGNOSTIC FACILITIES

8:33E–1.1 Scope and purpose

(a) 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 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 is necessary to provide safe, complete patient care, efficiently and effectively, at reasonable cost to the consumer.

(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 includes, 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 Inter–Society Commission for Heart Disease Resources (I.C.H.D.) and the New Jersey Cardiac Services Task Force support 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 popula-

tion examined by invasive techniques. Such problems occur ten 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 should be accessible promptly, either in-house or by immediate transfer, in the event of an emergency or complication. Therefore, outpatient catheterization must be performed in a laboratory that is physically part of 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 policy has been proposed for the more comprehensive cardiac surgery center and is 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.

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 diagnosis or limited treatment, such as the introduction of thrombolytic (clot dissolving) agents.

"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.

"Open heart surgery" refers to a procedure using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric" cardiac patients are those patients below the age of 16.

"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. PTCA has come to include other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

8:33E–1.3 Utilization of invasive cardiac diagnostic facilities

(a) Utilization standards are based on the number of patients upon whom invasive cardiac diagnostic procedures (cardiac catheterization) are performed. Cardiac catheterization is characterized as the entry into the systemic circulation and catheterization of the right heart and especially the left heart or angiography of the cardiac structures.

(b) Volume of patients diagnosed is not the only determinant or indicator of quality. The provision of advanced and invasive cardiac procedures require appropriate institutional infrastructure, including specialized nursing services, sophisticated laboratory technology, and in some cases well-developed non-cardiac specialty expertise (See N.J.A.C. 8:33E–1.3 and 1.4). However, some minimum volume is required to maintain the skills of the diagnostic team and to minimize costs per patient. The minimum acceptable number of adult cardiac catheterization patients per cardiac laboratory is 500 per year in order to maintain the skills of the catheterization team and the efficiency and effectiveness of the invasive cardiac diagnostic service. New services must attain this minimum utilization level within three years of operation. 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 withdraw Certificate of Need approval. The inability to achieve minimum utilization levels during the third year of operation will require the submission of a Certificate of Need to close the service. Existing services must achieve minimum utilization levels within one year of the effective date of this subchapter or be subject to administrative penalties.

(c) Applicants seeking to expand existing invasive cardiac diagnostic laboratory services must indicate conformance with all standards and criteria contained herein and document a minimum volume as defined at N.J.A.C. 8:33E–1.13 in the form of diagnostic catheterization procedures or cardiac catheterization equivalents (CEs) in the existing laboratory (or in each existing laboratory). A CE is considered to equal the average time required to perform a standard diagnostic cardiac catheterization. CEs for Percutaneous Transluminal Coronary Angioplasty (PTCA) (2.5 CEs) and initial (3.0 CEs) and repeat (1.5 CEs) Electrophysiology Studies (EPS) should be included if applicable.

(d) Each invasive cardiac diagnostic facility 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 New Jersey Cardiac Services Task Force, in its 1987 report, each physician must perform 50 cases a year with a minimum of 100 cases over a two year period. (This minimum case load may be accomplished at more than one laboratory.)

(e) Only centers with invasive pediatric cardiac diagnostic and pediatric cardiac surgery programs shall perform invasive cardiac diagnostic procedures on pediatric patients.

(f) Cardiac catheterization procedures must be performed in a hospital-based facility where inpatient support services are available on site.

(g) The following shall apply to invasive cardiac diagnostic facilities providing or seeking to provide complex electrophysiology studies (EPS) or percutaneous transluminal coronary angioplasty (PTCA):

1. Complex electrophysiology studies and percutaneous transluminal coronary angiography as defined in N.J.A.C. 8:33E–1.2 shall be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

Case Notes

Denial of Certificate of Need for cardiac-catherization 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 Facility personnel; requirements and responsibilities

(a) Each invasive cardiac diagnostic facility shall be staffed, at a minimum, by at least the following full-time personnel:

1. One physician;
2. One registered nurse; and
3. One technician.

(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 Sub–Specialty Board of Pediatric Cardiology of the American Board of Pediatrics or the Cardiovascular Sub–Specialty Board of the American Board of Internal Medicine. 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 and certification requirements for laboratory director contained in (b)1 above. In addition, all catheterizing physicians shall adhere to the minimum physician volume standards established by each laboratory in accordance with N.J.A.C. 8:33E–1.2(d).

i. Exceptions for incumbent directors and associate physicians to these minimum training and certification 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 and 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 (ICCU) experience, shall meet the licensing requirements specified at N.J.A.C. 8:43G–7.15(d), and must have knowledge of cardiovascular medications and experience with catheterization.

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 monitoring and recording technician shall be responsible for constant monitoring of physiologic data including the electrocardiogram and recording this information. This function can best be handled by a second cardiac catheterization technician or radiologic technician.

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

7. The electronic and radiological repair technician shall be highly trained and available for consultations regarding the operation and maintenance of all radio-

graphic and physiologic measuring and recording 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 native speaking clinical personnel available who can overcome language barriers and know and understand cultural differences among patients.

9. Hospitals providing invasive cardiac diagnostic services shall develop cardiology outreach mechanisms and referral services (for example, physician education, public information, primary care clinical services).

(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.

8:33E–1.5 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.

(c) Each peer review team shall include at least one cardiovascular surgeon from the surgical center to which surgical candidates are commonly referred.

8:33E–1.6 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–1.7 Association with cardiac surgical services

(a) Applicants providing cardiac diagnostic services without a surgery program shall have written agreements with institutions providing open heart surgery and catheterization, specifying a mechanism for insuring quality control, rapid referral for surgery, emergency back-up procedures and regular communication between the cardiologist performing catheterization and the surgeons to whom patients are referred. At least one of the referral agreements shall be written with a New Jersey cardiac center. In addition, one of the referral agreements shall be with a cardiac surgical center which is within one hour travel time from the diagnostic facility to insure prompt referral in the event of an emergency.

(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.

(c) The provision of complex electrophysiology services (EPS) and percutaneous transluminal coronary angiography (PTCA), as defined in this chapter, must be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

8:33E–1.8 Documentation of purchase and operational cost

The applicant shall 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–1.9 Statistical data required

At the request of the Commissioner, the facility shall maintain and provide basic statistical data on the operation of the program and report those data to the Department of Health on a quarterly basis and on a standardized form prepared 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, Center for Health Statistics, Room 405, CN 360, Trenton, New Jersey 08625.

8:33E–1.10 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–1.11 Compliance

Facilities which are providing cardiac diagnostic services without cardiac surgery shall meet the minimum criteria and standards outlined in this subchapter within one year following the effective date of this subchapter, and each year thereafter, or be subjected to 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.

8:33E–1.12 (Reserved)

8:33E–1.13 Submission of Certificate of Need Applications

(a) 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. Documentation should also be provided that indicates that other existing area providers of this invasive cardiac diagnostic service will not be jeopardized by the proposed new service.

(b) No more than one additional invasive cardiac diagnostic laboratory expansion will be approved in each local advisory board area for each call for certificate of need applications.

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.

(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.

(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.

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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 diagnosis or limited treatment, such as the introduction of thrombolytic (clot dissolving) agents.

"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.

"Open heart surgery" refers to a procedure using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric" cardiac patients are those patients below the age of 16.

"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. PTCA has come to include other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (e.g., excisional, laser) and arterial stenting procedures.

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. Utilization standards for the diagnostic services shall be based on the number of patients upon whom invasive cardiac diagnostic procedures are performed. The minimum acceptable number of adult cardiac catheterization patients per laboratory shall be 500 per year, in order to maintain the efficiency and the skills of the catheterization team.

i. Each invasive cardiac diagnostic service 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 cases a year with a minimum of 100 cases over a two year period must be maintained to preserve a consistent level of proficiency.

2. Surgical centers seeking to expand existing invasive cardiac diagnostic laboratory services must indicate conformance with all standards and criteria contained in this subchapter and document a minimum volume of cardiac catheterization procedures or cardiac catheterization equivalents (CEs) in the existing laboratory (or in each existing laboratory) as specified at N.J.A.C. 8:33E–2.15. A CE is considered to equal the average time required to perform a cardiac catheterization procedure. A percutaneous transluminal coronary angioplasty procedure will be considered as 2.5 CEs. An initial complex electrophysiology study will be 3.0 CEs and a repeat complex electrophysiology study will be 1.5 CEs.

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

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

5. Cardiac catheterization procedures must be performed in a hospital-based facility where inpatient support services are available on site.

(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, the operating surgeon and team or qualified alternate shall be on call. 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. There should 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. Each diagnostic facility shall be staffed, at a minimum, by the following full-time personnel:

i. One physician;

ii. One registered nurse; and

iii. One technician.

2. While the following functions shall be performed within each facility, more than one function may be executed by a single individual who has been appropriately cross-trained to perform the required functions:

i. The laboratory director (physician in charge) shall be the chief diagnostician within the unit, certified in cardiology by the Sub–Specialty Board of Pediatric Cardiology of the American Board of Pediatric or the Cardiovascular Sub–Specialty Board of the American Board of Internal Medicine. 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;

ii. Associate physicians may be assigned to the laboratory and shall meet the identical training and certification requirements for laboratory director contained in (c)2i above. In addition, all catheterizing physicians must adhere to the minimum physician volume standards established by each laboratory in accordance with N.J.A.C. 8:33E–2.3(c);

(1) 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.

iii. The registered nurse shall assist with administration of medications and the preparation and observation of the patient. The nurse shall have Intensive Care Cardiac Unit (ICCU) experience, shall meet the licensing requirements specified at N.J.A.C. 8:43G–7.15(d), and must have knowledge of cardiovascular medications and experience with catheterization;

iv. The cardiac catheterization technician shall handle blood samples and assist in the performance tests. The technicians shall help in the maintenance of equipment and supplies;

v. The monitoring and recording technician shall be responsible for constant monitoring of physiologic data, including the electrocardiogram, and recording this information. This job can best be handled by a second cardiac catheterization technician or radiologic technician;

vi. The 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;

vii. The electronic and radiological repair technician shall be highly trained and available for consultations regarding the operation and maintenance of all radiographic and physiologic measuring and recording 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;

viii. Hospitals providing invasive cardiac diagnostic and cardiac surgery services shall, to the extent possible, have native speaking clinical personnel available who can overcome language barriers and know and understand cultural differences among patients; and

ix. Hospitals providing invasive cardiac diagnostic and cardiac surgery services should develop cardiology outreach mechanisms and referral services (for example, physician education, public information, primary care clinical services).

3. One physician trained and experienced in cardiac catheterization shall be present in the room during all catheterization and angiographic procedures. A nurse and a technician, trained and experienced as required by this chapter, shall be present during all procedures.

(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. Because of the nature of care to be provided, cardiac surgical patients shall be grouped at the intermediate or acute care level for proper observation and treatment. During the preoperative stage when diagnostic work-ups are to be performed, six beds in a general medical/surgical unit shall be available for patients having an average length of stay of three to four days.

2. 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

At the request of the Commissioner, the facility will maintain and provide basic statistical data on the operation of the program and report that data to the Department of Health on a quarterly basis and on a standardized form prepared 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, Center for Health Statistics, Room 405, CN 360, Trenton, New Jersey 08625.

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 (Reserved)

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

(a) The Department of Health will only process certificate of need applications for the expansion of existing invasive cardiac diagnostic services within cardiac surgery centers 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, 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 during the most recent calendar year prior to submission of the application as specified at N.J.A.C. 8:33E–1.3(b) or at N.J.A.C. 8:33E–2.3(c), whichever is applicable; and where the applicant's level of utilization during the most recent calendar year prior to submission of the application exceeds 2,500 catheterization equivalents per laboratory. Documentation should also be provided that indicates that other existing area providers of this invasive cardiac service will not be jeopardized by the proposed new service.

(b) No more than one additional invasive cardiac diagnostic laboratory expansion will be approved in each local advisory board area for each call for certificate of need applications.