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.

Source and Effective Date

R.2006 d.263, effective June 19, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).

Chapter Expiration Date

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, expires on June 19, 2011.

Chapter Historical Note

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

Chapter 41, Certificate of Need: Cardiac Facilities, was adopted as R.1977 d.179 and d.180, effective May 23, 1977. See: 9 N.J.R. 171(a), 9 N.J.R. 171(b), 9 N.J.R. 268(c), 9 N.J.R. 268(d).

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

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

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

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

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

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

Pursuant to Executive Order No. 66(1978), Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, was readopted as R.2001 d.58, effective January 18, 2001. See: 32 N.J.R. 3890(a), 33 N.J.R. 653(a).

Chapter 33E, Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, was readopted by R.2006 d.263, effective June 19, 2006. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. CARDIAC DIAGNOSTIC FACILITIES

8:33E-1.1 Scope and purpose

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

1. As of February 20, 1996, a new category of invasive cardiac diagnostic catheterization facility was established to treat only low risk adult patients as defined at N.J.A.C. 8:33E-1.2.

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

(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. In the interest of patient care, then, it is important to encourage optimal utilization of diagnostic resources. It is also essential that in view of the invasive nature of the cardiac catheterization procedure and the extent of possible complications associated with these procedures, cardiac surgery services must be accessible promptly, either in-house or by immediate transfer, in the event of an emergency or complication. Finally, catheterization must be performed in a laboratory that is physically part of, and is a permanent structure within, a health care facility offering inpatient support services.

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

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote (a); in (b), rewrote last sentence; in (c), substituted "optimal" for "maximum" and deleted "the State's existing" preceding "diagnostic resources".
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In (a) and (b), rewrote the last sentence; in (c), deleted the former second and third sentences.
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
In (a), substituted "percutaneous coronary intervention (PCI)" for "PTCA".

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, PCI, and complex EPS studies.

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

Procedures which intend to induce ventricular or supraventricular tachycardia;

Activation sequence mapping of cardiac tachyarrhythmias;

Electrode catheter ablative procedures;

Implantation of anti-tachyarrhythmia devices and implantable cardioverter defibrillators.

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

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

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without cardiac surgery backup. These facilities have laboratories which must meet the requirement of procedures performed on at least 400 patients annually.