

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 Appendix A was repealed by R.1982 d.24.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. 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.