

CHAPTER 33**CERTIFICATE OF NEED: APPLICATION AND REVIEW PROCESS****Authority**

N.J.S.A. 26:2H-1 et seq.

Source and Effective Date

R.1998 d.278, effective June 1, 1998.
See: 30 N.J.R. 1005(a), 30 N.J.R. 1991(a).

Executive Order No. 66(1978) Expiration Date

Chapter 33, Certificate of Need: Application and Review Process, expires on June 1, 2003.

Chapter Historical Note

Chapter 33 was adopted as R.1972 d.93, effective on May 11, 1972. See: 4 N.J.R. 25(a), 4 N.J.R. 124(a). Chapter 33 was amended by R.1975 d.315, effective December 1, 1975. See: 7 N.J.R. 362(a), 7 N.J.R. 503(a); R.1979 d.283, effective July 20, 1979. See: 11 N.J.R. 174(a), 11 N.J.R. 439(a); R.1980 d. 36, effective January 17, 1980. See: 11 N.J.R. 620(a), 12 N.J.R. 75(e); R.1980 d.123, effective March 20, 1980. See: 12 N.J.R. 73(d), 12 N.J.R. 186(c); R.1981 d.296, effective August 6, 1981. See: 13 N.J.R. 267(a), 13 N.J.R. 487(b); and R.1983 d.205, effective June 6, 1983. See: 15 N.J.R. 307(b), 15 N.J.R. 920(c).

Pursuant to Executive Order No. 66(1978), Chapter 33 was readopted as R.1983 d.604, effective December 14, 1983. See: 15 N.J.R. 1708(b), 16 N.J.R. 48(a). Chapter 33 was repealed and a new Chapter 33, Certificate of Need: Application and Review, was adopted by R.1985 d.498, effective October 7, 1985. See: 17 N.J.R. 1190(a), 17 N.J.R. 2402(a).

Pursuant to Executive Order No. 66(1978), Chapter 33 was readopted as R.1990 d.417, effective July 27, 1990. See: 22 N.J.R. 1494(a), 22 N.J.R. 2506(a).

Subchapters 1 through 4 were repealed and a new Subchapter 1, General Provisions; Subchapter 2, Applicability of Certificate of Need Requirements; Subchapter 3, Types of Certificate of Need Applications; Subchapter 4, The Review Process; and Subchapter 5, Expedited Review Process, were adopted as new rules by R.1992 d.342, effective September 8, 1992. See: 24 N.J.R. 2222(a), 24 N.J.R. 3104(a). As a part of R.1992 d.342, Section 5.1 was recodified as 6.1. Subchapter 6, Certificate of Need Moratorium, was repealed and a new Subchapter 6, Certificate of Need Exemptions, was adopted as new rules by R.1993 d.442, effective September 7, 1993. See: 25 N.J.R. 2171(a), 25 N.J.R. 4129(a). Subchapter 7, Direct Review Process, was adopted as R.1996 d.101, effective February 20, 1996. See: 27 N.J.R. 4179(a), 28 N.J.R. 1228(a). Pursuant to Executive Order No. 66(1978), Chapter 33, Certificate of Need: Application and Review, expired on September 8, 1997.

Chapter 33, Certificate of Need: Application and Review Process, was adopted as new rules by R.1998 d.278, effective June 1, 1998. See: Source and Effective Date.

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The following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise:

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

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

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

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

“Satellite hospital” means a non-inner city licensed acute care hospital which is a member of a hospital system containing an inner city teaching hospital and which is permitted to provide invasive therapeutic cardiac services

through implementation of an inner city cardiac satellite demonstration project, in accordance with these rules.

SUBCHAPTER 2. (RESERVED)

SUBCHAPTER 3. TYPES OF CERTIFICATE OF
NEED APPLICATIONS

8:33-3.1 through 8:33-3.10 (Reserved)

8:33-3.11 Demonstration and research projects

(a)-(b) (Reserved)

(c) This subsection sets forth the requirements for an inner city cardiac satellite demonstration project:

1. The purpose of an inner city cardiac satellite demonstration project, as defined in N.J.A.C. 8:33-1.3, is to test the hypothesis that permitting a licensed inner city acute care teaching hospital to provide invasive therapeutic cardiac services at a satellite hospital within the same hospital system shall maintain or improve the financial stability of the inner city hospital and promote the continued provision of the full range of services and programs which it provides. This project allows qualifying hospital systems to generate greater revenue for inner city hospitals by enabling them to provide invasive therapeutic cardiac services at a satellite hospital, the benefits of which shall then be credited to the inner city hospital, thereby enabling the inner city hospital to improve access to and the quality of invasive therapeutic cardiac services to medically underserved populations.

2. Inner city cardiac satellite demonstration projects shall obtain a certificate of need pursuant to the expedited review process set forth in N.J.A.C. 8:33-5. All activities of both the inner city hospital and the satellite hospital shall be governed by the rules concerning cardiac surgery centers, at N.J.A.C. 8:33E.

3. In order to implement the demonstration project gradually, the Department shall accept no more than two certificate of need applications, for cardiac satellite demonstration projects in any consecutive 24-month period, beginning on July 1, 1998. In addition to meeting the remaining criteria set forth in this subsection, only those applicants providing convincing evidence that the proposed project shall increase access to invasive therapeutic cardiac services among minority and medically underserved populations through the increased revenue reasonably expected through implementation of the project, shall be accepted.

4. An inner city cardiac satellite demonstration project shall submit an application to the Department of Health and Senior Services that, at a minimum, demonstrates that the proposed inner city cardiac satellite demonstration project satisfies the following criteria:

i. The inner city hospital shall be part of a multi hospital system and shall be a licensed acute care teaching hospital which provides a comprehensive complement of invasive therapeutic cardiac services (that is, coronary artery by-pass graft, percutaneous transluminal coronary angioplasty, complex electrophysiology study);

ii. Prior to the provision of the invasive therapeutic cardiac services at the satellite hospital, and on a periodic basis thereafter as determined by the Department, the inner city hospital and the satellite hospital shall each comply with all licensure criteria governing the provision of invasive therapeutic cardiac services, including those contained within N.J.A.C. 8:43G-7;

iii. Net revenues generated from the provision of invasive therapeutic cardiac services at the satellite hospital shall be utilized to benefit the inner city hospital. Upon application, the inner city hospital shall provide to the Department a report prepared by an independent accounting firm approved by the Department. The report shall provide an estimated projection of the amount of net revenues and expenses expected as a result of the implementation of an inner city cardiac satellite demonstration project, together with the methodology utilized to calculate the reported net revenues. The methodology shall comport with fair market valuation of all costs and revenues. The report shall further set forth a plan demonstrating the manner in which reported net revenues shall be used to increase access to and the quality of invasive therapeutic cardiac services at the inner city hospital and to promote, generally, the financial stability of the inner city hospital and the continued provision of the full range of services and programs which it provides. Upon the conclusion of the first calendar year of operation of the inner city cardiac satellite demonstration project, and each year of operation thereafter, the inner city hospital shall provide to the Department an accounting, in a standardized format to be determined by the Department, containing the net revenues that have been utilized to benefit the inner city hospitals. In addition, a complete financial report from the satellite hospital shall be submitted to the Department, including all expenses and other financial information related to the invasive therapeutic cardiac center, and the services it provides. This report shall be submitted to the Department within 60 days after the close of each calendar year;

iv. The provision of invasive therapeutic cardiac services at a satellite hospital in accordance with this subsection shall not result in a diminution of the volume or quality of services at the inner city hospital, as compared to the volume and quality of services prior to the initiation of the demonstration project. Volume shall not decrease 20 percent or more below the previous level, and the quality shall not decrease, as measured by risk-adjusted mortality rates, compliance with nationally-recognized quality improvement initiatives and other measures as determined by the Department on a case-by-case basis, depending upon the facts and circumstances. Upon application, the inner city hospital shall submit a plan that demonstrates how the volume and quality of the invasive therapeutic cardiac services at the inner city hospital will be maintained. Notwithstanding the foregoing, the inner city hospital shall satisfy the regulatory requirements set forth at N.J.A.C. 8:33E-2.3 that are applicable to invasive therapeutic cardiac procedures, governing volume and quality of services. If the Department determines that the volume at the inner city hospital has decreased by 20 percent or more, or the quality is lower to a degree, for a consecutive 12-month period, the Department shall have the authority to rescind the satellite hospital's license to operate its invasive therapeutic cardiac services, upon notice to the inner city hospital and a six-month period to cure the deficiencies. The Department's determination to rescind the inner city hospital's license hereunder shall be final;

v. The provision of invasive therapeutic cardiac services at the satellite hospital division shall be subject to the governance of the inner city hospital and operated in accordance with the policies, procedures, and protocols of the inner city hospital which shall hold the license;

vi. Every inner city cardiac satellite demonstration project shall record and maintain data on the operation of the project, the patients served, the outreach to minority and indigent communities, and other information requested of each project by the Department. Such data shall be reported in a standardized format determined by the Department, and provided to the Department on a quarterly basis within 30 days after the close of each quarter;

vii. The inner city hospital shall ensure the provision of invasive therapeutic cardiac services at both the satellite hospital and the inner city hospital and shall assure that both hospitals comply and continue to comply with all applicable licensure rules.

5. All facilities seeking to initiate an inner city cardiac satellite demonstration project pursuant to an approved certificate of need issued in accordance with the demonstration criteria described in this subchapter shall be initially licensed on an annual basis, in accordance with the provisions of N.J.A.C. 8:43G.

6. Licenses for inner city cardiac satellite demonstration project facilities 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.

7. 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.

SUBCHAPTER 4. (RESERVED)

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.1 Statement of purpose

(a) The expedited review process shall be used for the following specific applications:

1.-23. (Reserved)

24. Establishment of an inner city cardiac satellite demonstration project as defined at N.J.A.C. 8:33-1.3 and consistent with the criteria set forth at N.J.A.C. 8:33-3.11.

(b) (Reserved)

8:33-5.2 through 8:33-5.4 (Reserved)

SUBCHAPTERS 6 THROUGH 7. (RESERVED)

APPENDIX

(RESERVED)