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HEALTH

HEALTH SYSTEMS BRANCH

CERTIFICATE OF NEED AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Certificate of Need: Application and Review Process

Proposed Readoption with Amendments: N.J.A.C. 8:33

Proposed Repeals and New Rules: N.J.A.C. 8:33 Appendices B, C, D, and E

Authorized By: Mary E. O'Dowd, M.P.H., Commissioner, Department of Health (with the approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2015-014.

Submit written comments electronically to http://www.nj.gov/health/legal/ecomments.shtml by April 3, 2015, or by regular mail postmarked by April 3, 2015, to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

N.J.A.C. 8:33, Certificate of Need: Application and Review Process, was scheduled to expire on December 21, 2014, in accordance with N.J.S.A. 52:14B-5.1 and Executive Order No. 66 (1978). The New Jersey Department of Health (Department) proposes to readopt the chapter with amendments, repeals, and new rules. In accordance with N.J.S.A. 52:14B-5.1.c(2) and N.J.A.C. 1:30-6.4(g), the filing of this notice of proposal with the Office of Administrative Law on December 22, 2014, operated to extend the expiration date of N.J.A.C. 8:33 180 days to June 19, 2015.

The Department has reviewed N.J.A.C. 8:33 and has determined that, subject to the proposed amendments, repeals, and new rules described below, the existing chapter continues to be necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which it was originally promulgated. The rules proposed for readoption have provided, and with the proposed amendments, repeals, and new rules would continue to provide, the regulatory framework by which the Department assures access to high quality health care services and maintains the certificate of need process for certain health care facilities and services as set forth in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.).

The Department promulgated rules at N.J.A.C. 8:33, Certificate of Need: Application and Review Process, which became effective May 11, 1972. 4 N.J.R. 25(a) and 124(a). Thereafter, the Department periodically amended the chapter as follows: effective December 1, 1975, 7 N.J.R. 362(a) and 502(a); effective July 20, 1979, 11 N.J.R. 174(a) and 439(a); effective January 17, 1980, 11 N.J.R. 620(a) and 12 N.J.R.

75(e); effective March 20, 1980, 12 N.J.R. 73(d) and 186(c); effective August 6, 1981, 13 N.J.R. 267(a) and 487(b); and effective June 6, 1983. 15 N.J.R. 307(b) and 920(c).

Effective December 14, 1983, the Department readopted Chapter 33, and, effective January 3, 1984, the Department amended the chapter. 15 N.J.R. 1708(b) and 16 N.J.R. 48(a).

Effective October 7, 1985, the Department repealed Chapter 33 and adopted a new Chapter 33, Certificate of Need: Application and Review Process. 17 N.J.R. 1190(a) and 2402(a).

Effective July 27, 1990, the Department readopted Chapter 33, Certificate of Need: Application and Review Process. 22 N.J.R. 1494(a) and 2506(a).

Effective September 8, 1992, the Department repealed Subchapters 1 through 4, recodified existing N.J.A.C. 8:33-5.1 as new N.J.A.C. 8:33-6.1, and adopted the following as new rules: 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. 24 N.J.R. 2222(a) and 3104(a).

Effective September 7, 1993, the Department adopted amendments to existing Chapter 33, repealed existing Subchapter 6, Certificate of Need Moratorium, and adopted as new rules Subchapter 6, Certificate of Need Exemptions, and recodified with amendments existing N.J.A.C. 8:33-5, Appendix 1, 2, and 3 as N.J.A.C. 8:33 Appendices 1, 2, and 3. 25 N.J.R. 2171(a) and 4129(a).

Effective February 20, 1996, the Department adopted amendments to existing Chapter 33 and established new rules at Subchapter 7, Direct Review Process. 27 N.J.R. 4179(a) and 28 N.J.R. 1228(a).

Pursuant to Executive Order No. 66 (1978), Chapter 8:33, Certificate of Need: Application and Review Process, expired September 8, 1997.

Effective June 15, 1998, the Department adopted Chapter 33 as new rules. 30 N.J.R. 303(a) and 2270(b). Effective June 1, 1998, the Department adopted new rules at N.J.A.C. 8:33-1.3, 3.11, and 5.1, to establish the "inner city cardiac demonstration project." 30 N.J.R. 1005(a) and 1991(a).

On January 22, 2002, the Department proposed the readoption with amendments, repeals, and new rules for Chapter 8:33, Certificate of Need: Application and Review Process. 34 N.J.R. 458(a). On March 18, 2002, pursuant to N.J.A.C. 1:30-5.4, the Department issued a notice to extend the public comment period for this proposed rulemaking from February 22, 2002 to March 25, 2002, because of the extensive nature of the proposed amendments, repeals, and new rules. 34 N.J.R. 1246(a). Effective July 3, 2002, the Department readopted existing Chapter 8:33. 34 N.J.R. 2814(a). Effective August 5, 2002, the Department amended existing N.J.A.C. 8:33; repealed and adopted a new rule at N.J.A.C. 8:33-3.7; repealed existing N.J.A.C. 8:33-2.3, 2.4, 3.6, 4.11, 4.12, 4.14, and 7, and Appendix Exhibits 1 and 4; and adopted new rules at Subchapter 7, Direct Review Process. 34 N.J.R. 458(a) and 2814(a).

Effective December 21, 2007, the Department readopted Chapter 33, Certificate of Need: Application and Review Process, and renamed the existing Appendix as Appendix A, effective January 22, 2008.

Effective October 21, 2013, the Department amended Subchapter 3, Demonstration and Research Projects, to extend the expiration of the Atlantic Cardiovascular Patient Outcomes Research Team demonstration project until December 31, 2014. 45 N.J.R. 191(a) and 2330(c).

Following is a summary of the rules proposed for readoption:

Subchapter 1 would continue to set forth the general provisions of the chapter, including the scope and purpose (N.J.A.C. 8:33-1.1); general statements regarding the public policy of the State and rules of general application with respect to the certificate of need process (N.J.A.C. 8:33-1.2); and definitions (N.J.A.C. 8:33-1.3).

Subchapter 2 provides a description of the applicability of certificate of need requirements, including the two types of certificate of need review, full and expedited review, and whether a particular health care entity or modality of health care would be subject to the provisions of the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.).

Subchapter 3 includes N.J.A.C. 8:33-3.1, which describes the types of certificate of need applications, including the initiation of a health care service. N.J.A.C. 8:33-3.2 describes the termination or discontinuance of a service or facility and the reduction of licensed bed capacity. N.J.A.C. 8:33-3.3 describes transfers of ownership of a facility or service. N.J.A.C. 8:33-3.4 describes changes in licensed beds or services. N.J.A.C. 8:33-3.5 describes buildings requirements. N.J.A.C. 8:33-3.7 and 3.8 address major and minor moveable equipment requirements, respectively. N.J.A.C. 8:33-3.9 establishes requirements for changes in cost and/or scope of the project. The subchapter also includes a section that describes the criteria for the duration of an

unimplemented certificate of need (N.J.A.C. 8:33-3.10). N.J.A.C. 8:33-3.11 addresses demonstration and research projects.

Subchapter 4 would continue to detail the administrative process for the full certificate of need review process, including certificate of need application review cycles and a schedule of submission dates for batched certificate of need applications (N.J.A.C. 8:33-4.1(a)). Specifically, the full review process for non-batched applications would continue to include 12 review cycles, with the beginning of each cycle scheduled to take place on the first business day of each month (N.J.A.C. 8:33-4.1(a)1). N.J.A.C. 8:33-4.1(a)2 would continue to identify the full review schedule for batched applications including the deadline for submission dates. N.J.A.C. 8:33-4.1(a)3 would continue to note that acceptance of batched applications does not constitute a finding by the Department of need for additional beds or services. N.J.A.C. 8:33-4.1(a)4 would continue to provide for special calls by the Commissioner of the Department (Commissioner) for services with longer than annual submission schedules upon a finding of extraordinary circumstances. N.J.A.C. 8:33-4.1(a)5 would continue to provide for the Department's review of the schedule for adequacy at least every five years. N.J.A.C. 8:33-4.1(a)6 would continue to require new cardiac surgery services to follow the procedures specified at N.J.A.C. 8:33E.

N.J.A.C. 8:33-4.1(b) would continue to require the Commissioner to render a decision on expedited review applications no later than 90 days after the beginning of each review cycle, unless otherwise specified by rule or notice. The readoption would also require the Department to review on an annual basis its compliance with the 90-day review timeframe (N.J.A.C. 8:33-4.1(c)). Potential certificate of need applicants

would continue to be encouraged to contact the Department to examine the relationship of a project with applicable plans, guidelines, and criteria (N.J.A.C. 8:33-4.2).

N.J.A.C. 8:33-4.3 provides for the number of certificate of need applications that are required to be submitted to the Department, as well as the contact information and application fees, which are proposed for amendment as noted below. .

N.J.A.C. 8:33-4.4 would continue to provide general filing requirements, including: proof of ownership of the proposed site (N.J.A.C. 8:33-4.4(a)); identification of all principals involved in the ownership of the proposed facility (N.J.A.C. 8:33-4.4(b)); the name and address of the registered agent, if the applicant is a registered corporation (N.J.A.C. 8:33-4.4(c)); the requirement that the proposed operator of the facility file and sign the application (N.J.A.C. 8:33-4.4(d)); and, that the Department would determine the application not acceptable for processing in the event the applicant fails to fully comply with the general filing provisions of this section (N.J.A.C. 8:33-4.4(e)).

N.J.A.C. 8:33-4.5 provides for a completeness review process and N.J.A.C. 8:33-4.6 provides the criteria for modification of a certificate of need application once it has been submitted to the Department.

N.J.A.C. 8:33-4.7 and 4.8 set forth the policies regarding the deferral of applications and the withdrawal of applications, respectively. N.J.A.C. 8:33-4.9 sets forth the general criteria for certificate of need review.

N.J.A.C. 8:33-4.10 contains specific criteria for review, including the promotion of access to care by low income, racial and ethnic minorities, women, disabled persons, and persons with HIV infections. This section would continue to include track record

provisions to assure character and competence and quality of care. N.J.A.C. 8:33-4.11 and 4.12 would continue as reserved sections. N.J.A.C. 8:33-4.13 would continue to set forth the role of the State Health Planning Board in certificate of need applications that are subject to full review. N.J.A.C. 8:33-4.14 would continue to be reserved. N.J.A.C. 8:33-4.15 would continue to set forth the procedures for the Commissioner's review. N.J.A.C. 8:33-4.16 would continue to set forth policies regarding the placement of conditions on certificate of need approvals.

Subchapter 5 sets forth the Department's expedited certificate of need review process. N.J.A.C. 8:33-5.1(a) would continue to provide a list of health care service categories that are to be evaluated by the Department under the expedited review process. N.J.A.C. 8:33-5.1(b) would continue to permit the expedited review process to be used in lieu of the full review process in emergency situations that demand rapid action or for those projects where there is minimal impact on the health care system as a whole. N.J.A.C. 8:33-5.2 would continue to set forth the manner in which expedited review applications are processed. N.J.A.C. 8:33-5.3 would continue to set forth the general requirements that are to be included in expedited review applications. N.J.A.C. 8:33-5.4 would continue to set forth specific requirements for expedited review applications.

Subchapter 6 would continue to set forth the health care services that are exempt from the certificate of need process that are consistent with the provisions of the Health Care Facilities Planning Act, as amended. N.J.S.A. 26:2H-7.a.

Subchapter 7 would continue to be reserved.

N.J.A.C. 8:33 Appendix A includes exhibits that list the types of health care services that continue to require a certificate of need (Exhibit 1), that provide examples of major movable equipment (Exhibit 2), and that provide a summary listing of certificate of need activities and the type of certificate of need review that is required or if the activity is exempt from the review requirement (Exhibit 3).

N.J.A.C. 8:33 Appendix B contains form CN-1, Full Review Certificate of Need Application for Long Term Care Facilities: General Long Term Care Beds; Specialized Long Term Care Beds.

N.J.A.C. 8:33 Appendix C contains form CN-3, Certificate of Need Application for Hospital-Related Projects.

N.J.A.C. 8:33 Appendix D contains form CN-4, Certificate of Need Application for Designation as a Perinatal Facility.

N.J.A.C. 8:33 Appendix E contains form CN-19, Certificate of Need Application - Expedited Review for Facilities and Services Identified at N.J.A.C. 8:33-5.1(a).

Following is a summary of the proposed amendments, repeals, and new rules:

The Department proposes to amend references to the Department throughout the chapter to reflect the change in the name of the Department from the “New Jersey State Department of Health and Senior Services” to the “New Jersey Department of Health” pursuant to N.J.S.A. 26:1A-2.1 (approved June 29, 2012).

The Department is proposing to delete definitions at N.J.A.C. 8:33-1.3 for the following terms: “bloodless surgery,” “elective angioplasty demonstration project,” “inner city cardiac satellite demonstration project,” “inner city hospital,” and “satellite hospital.” These changes are necessary because the Department is proposing to delete

provisions establishing inner city cardiac satellite demonstration projects, bloodless surgery demonstration projects, and the elective angioplasty demonstration project at N.J.A.C. 8:33-3.11(c), (d), and (e), respectively.

At N.J.A.C. 8:33-1.3, the definition of “Atlantic Cardiovascular Patient Outcomes Research Team trial” or “Atlantic C-PORT-E trial,” is proposed for deletion and replaced with a new definition of “Atlantic C-PORT-E registry,” as the trial ended and was replaced by the registry.

The Department proposes to add definitions at N.J.A.C. 8:33-1.3 of the following terms: “American Board of Internal Medicine,” “applicant hospital,” “atherectomy device,” “Atlantic C-PORT-E Manual of Operations,” “Atlantic C-PORT-E Study,” “Cardiovascular Subspecialty Board of the American Board of Internal Medicine,” “Data Monitor,” “elective,” “in-stent restenosis,” “interventionalist,” “participating hospital,” “percutaneous coronary intervention or PCI,” “primary,” and “State elective angioplasty demonstration project.”

The Department proposes to amend existing N.J.A.C. 8:33-3.11(c) and (d) to delete the existing subsections for inner city cardiac satellite and bloodless surgery demonstration projects because there is no longer any need for demonstration projects for these categories of cardiac service delivery. The Department has not received any hospital proposals for these two demonstration projects for the past decade and attributes this lack of interest to technological advances in surgical techniques and a leveling-off of cardiac surgery demand Statewide, which peaked a decade ago. The Department maintains a mechanism to obtain cardiac surgery service licensure through the cardiac surgery petition process at N.J.A.C. 8:33E-2.14.

The Department proposes to amend existing N.J.A.C. 8:33-3.11 to delete subsection (e), which establishes the Atlantic Cardiovascular Patient Outcomes Research Team trial, and which is expected to cease on December 31, 2014.

The Department proposes new N.J.A.C. 8:33-3.11(c) to establish a State elective angioplasty demonstration project. The purpose of the State demonstration project would be to facilitate scientifically rigorous collection and analysis of data that would contribute significantly to the evidence base in New Jersey on the safety and efficacy of elective PCI with and without on-site CABG surgical back-up and compare it to the results of the Atlantic C-PORT-E Study and registry. The State demonstration project also would permit those hospitals currently participating in the Atlantic C-PORT-E registry to apply for a certificate of need for the project under expedited review. Approval would permit these facilities to provide the same services by documenting continued compliance with licensing requirements for elective PCI. The Department intends to extend the licenses of the 11 hospitals participating in the existing elective angioplasty demonstration project until the Department can issue new licenses under the proposed amendments. As proposed, hospitals licensed to perform elective PCI in the existing elective angioplasty demonstration project that elect to participate in the State demonstration project would submit to the Department a certificate of need application under the expedited review process within 30 days of the effective date of the amended rules. To assure quality, provide clinical oversight of the State demonstration project, and assist the Department with the collection and analysis of the data, the Department is also proposing to designate a Data Monitor that would be responsible for receiving patient level data to monitor for adverse events and to

promptly report safety concerns to the Department. The Data Monitor would also assist the Department in evaluating the safety and efficacy of the State demonstration project, and evaluating whether the results of the State demonstration project are consistent with the results of the C-PORT-E Study. The data that participating hospitals would report to the Data Monitor is the same data that must be reported to the American College of Cardiology's National Cardiovascular Data Registry. https://www.ncdr.com/WebNCDR/home/dataquality. The State demonstration project is expected to last 18 months, but will continue until (i) the promulgation of new rules at N.J.A.C. 8:33E that establish minimum standards for hospitals performing elective angioplasty without cardiac surgery backup; and (ii) the issuance of licenses under those rules. The new rules would authorize the Department to issue a Statewide call for certificate of need applications for a limited number of hospitals to provide elective PCI without cardiac surgery on-site, and those applications would be subject to the full review process.

The Department proposes to amend N.J.A.C. 8:33-4.3(a) to provide a link to the Department's website where an applicant may obtain full review certificate of need applications. The proposed amendment also would require the applicant to submit the application in electronic media, in addition to the paper copies that are already required.

The Department proposes to amend N.J.A.C. 8:33-5.2(e) to direct applicants to the Department's website to obtain copies of the expedited review application. The proposed amendment also would require applicants to submit one copy of the application in electronic media, in addition to the paper copies that are already required.

The proposed repeals of N.J.A.C. 8:33 Appendices B, C, D, and E would be replaced by proposed new rules at N.J.A.C. 8:33 Appendices B, C, D, and E that would contain new CN-1, CN-3, CN-4, and CN-19 forms, respectively. Specifically, the new forms would add language to include one completed certificate of need application in electronic media with the required number of paper copies of the application to reflect the changes proposed at N.J.A.C. 8:33-4.2 and 5.3.

In addition, the Department is proposing to amend form CN-19 at N.J.A.C. 8:33 Appendix E by deleting the Attachments Checklist, which serves as a reminder for the submission of certificate of need applications for expedited review. The Department intends to develop a new checklist that would not be part of the application form and would be available with the certificate of need application forms on the Department's website at: http://web.doh.state.nj.us/apps2/forms/subforms.aspx?pro=healthfacilities.

As the Department has provided a 60-day comment period for this notice of proposal, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is exempt from the rulemaking calendar requirement, as set forth at N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Health Care Facilities Planning Act recognizes as "public policy of the State that hospitals and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost are of vital concern to the public health." N.J.S.A. 26:2H-1 et seq. The regulatory structure for the State's health care delivery system in the 1970s was predicated on the belief that health care costs are best managed by government allocation of health care resources.

The 1990s were a decade of rapid change in New Jersey's healthcare delivery system, which included the evolution of market-based means of controlling costs, most notably the growth of managed care, and the development of new medical techniques, and innovations in medical technology. In 1992, in response to these changes, the State began to dismantle the existing regulatory scheme by eliminating hospital rate setting through the enactment of the Health Care Reform Act. N.J.S.A. 26:2H-18.51 et seq. In 1998, the Certificate of Need Reform Act eliminated the certificate of need requirement for many health care services. N.J.S.A. 26:2H-7.a. At that time, the Legislature also recognized the benefit derived by the State certifying need for certain health care services, such as elective angioplasty, to preserve the quality of, and access to, the health care delivery system in New Jersey.

The Department is proposing the rules for the readoption with amendments, repeals, and new rules of this chapter, which incorporates the reforms of the 1990s and maintains the structure to ensure high quality health care services throughout New Jersey established in the 1970s. The rules proposed for readoption would continue the process by which all health care services that require full certificate of need review are considered by the State Health Planning Board at a public meeting where the Department must offer adequate notice and an opportunity for public comment.

Economic Impact

The proposed readoption of the rules at Chapter 33 with amendments, repeals, and new rules would continue to implement the intent of the Certificate of Need Reform Act by promoting efficiency in the State's health care delivery system, continuing to

certify the need for certain health care services to maintain quality health care throughout the State. (N.J.S.A. 26:2H-7.a) The costs to providers for health services that remain subject to certificate of need would be dependent on each facility's need to renovate or construct physical space required for the proposed service. The costs incurred in this process must be considered by each applicant and balanced against the anticipated increases in patient census and volume of services and the reimbursement from the addition of new or expanded services.

The Department notes that the proposed amendments would offer the 11 hospitals currently providing elective PCI without on-site cardiac surgery the opportunity to participate in a Statewide demonstration project. An eligible hospital that elects to participate in the Statewide demonstration project shall submit to the Department a completed certificate of need application under the expedited review process in accordance with N.J.A.C. 8:33-5.2, along with a non-refundable application fee in the amount of $7,500. At their election, the hospitals likely would incur costs the Department anticipates as less than the annual cost of their current participation in the Atlantic C-PORT-E registry. The Department expects the Atlantic C-PORT-E registry to cease at year's end. No additional costs to providers or consumers of cardiac services are anticipated as a result of these proposed amendments.

The proposed amendments to N.J.A.C. 8:33-4.3 and 5.2 would place an additional requirement on an applicant to submit a certificate of need application in electronic media as well as paper. However, the Department expects the impact of this requirement on certificate of need applicants would be minimal.

Federal Standards Statement

The Department is neither proposing to readopt N.J.A.C. 8:33, nor proposing the proposed amendments, repeals, and new rules under the authority of, or in order to implement, comply with, or participate in any Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

Jobs Impact

The rules proposed for readoption with amendments, repeals, and new rules would have no impact on jobs because they would neither create nor reduce jobs. The number of providers of elective PCI is not expected to change under the rules proposed for readoption with amendments, repeals, and new rules.

Agriculture Industry Impact

The rules proposed for readoption with amendments, repeals, and new rules have not had, nor would they have, an impact upon the agriculture industry in New Jersey.

Regulatory Flexibility Statement

The rules proposed for readoption with amendments, repeals, and new rules are applicable only to hospitals, which employ well over 100 full-time employees. Thus, they are not small businesses as that term is defined in N.J.S.A. 52:14B-16 et seq., and no regulatory flexibility analysis is necessary.

Housing Affordability Impact Analysis

The rules proposed for readoption with amendments, repeals, and new rules would have no impact on affordable housing in New Jersey and would not evoke a change in the average costs associated with housing because the proposed rulemaking pertains to the standards of review in the certificate of need process for licensed health care facilities and has nothing to do with housing.

Smart Growth Development Impact Analysis

The rules proposed for readoption with amendments, repeals, and new rules would have no impact on smart growth and would not evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed rulemaking pertains to the standards of review in the certificate of need process for licensed health care facilities and has nothing to do with housing.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:33.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:33 Appendices B, C, D, and E.

Full text of the proposed amendments and new rules follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

8:33-1.1 Purpose and scope

(a)-(b) (No change.)

(c) All inquiries regarding certificate of need matters should be directed to:

Office of Certificate of Need and Healthcare Facility Licensure

New Jersey [State] Department of Health [and Senior Services]

PO Box 358

Trenton, [New Jersey] **NJ** 08625-0358

(609) 292-6552 and 292-7228

8:33-1.3 Definitions

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

…

"**American Board of Internal Medicine" or "ABIM" means one of the 24 certifying boards under the American Board of Medical Specialties umbrella, which sets the standards for physician certification in the United States and assists its member boards in developing and implementing standards to evaluate and certify physician specialists, and which is located at 510 Walnut Street, Suite 1700, Philadelphia, PA 19106 – 3699, and can be reached by telephone at 1.800.441.ABIM, or accessed through its website at: www.abim.org**

...

"Applicant hospital" means a hospital that has submitted a certificate of need application to perform elective PCI in the State demonstration project.

…

"Atherectomy device" means a device (directional, rotational, orbital or 360 degree, excisional laser, or as may be developed or used) to remove the plaque burden within a coronary artery.

"Atlantic C-PORT-E Manual of Operations" means the manual of operations that governed participation in the Atlantic C-PORT-E registry.

["Atlantic Cardiovascular Patient Outcomes Research Team trial" or "Atlantic C-PORT-E trial" means the multi-state, randomized clinical trial being conducted by the Atlantic Cardiovascular Patient Outcomes Research Team under the direction of Thomas Aversano, M.D., Johns Hopkins Medical Institutions comparing outcomes of elective PCI at hospitals with and without on-site cardiac surgery.

1. Atlantic C-PORT-E trial documents and other information can be obtained by contacting Thomas Aversano, M.D., Medical Director, Atlantic C-PORT-E, Johns Hopkins Medical Institutions, 5501 Hopkins Bayview Circle, JHACC 1B.40, Baltimore, Maryland 21224 (410) 550-9820, http://www.cport.org/atlantic_cport_introductions_body.htm.]

"Atlantic C-PORT-E registry" means the multi-state repository of patient-specific elective angioplasty data in hospital settings that are without on-site cardiac surgery conducted by the Atlantic Cardiovascular Patient Outcomes Research Team under the direction of Thomas Aversano, M.D., Johns Hopkins Medical Institutions, which compares outcomes of elective PCI at hospitals with and without on-site cardiac surgery, and which terminated on or around December 31, 2014.

"Atlantic C-PORT-E Study" or "C-PORT-E Study" means the multi-state, randomized clinical trial conducted by the Atlantic Cardiovascular Patient Outcomes Research Team under the direction of Thomas Aversano, M.D., Johns Hopkins Medical Institutions that compared outcomes of elective PCI at hospitals with and without on-site cardiac surgery, the results of which were published in the New England Journal of Medicine in 2012.

…

["Bloodless surgery" means the performance of surgery in a general hospital without the use of blood transfusion, including, but not limited to, adult cardiac surgery and exclusive of pediatric cardiac surgery, solid organ transplantation, high risk perinatal, and trauma surgery.]

…

"Cardiovascular Subspecialty Board of the American Board of Internal Medicine" means the subspecialty board of the ABIM that confers physician certification in Interventional Cardiology.

…

"Data Monitor" means an individual or entity that the Department designates to:

1. Ensure quality and provide clinical oversight of the State demonstration project;

2. Receive patient level data from each participating hospital;

3. Monitor for adverse events;

4. Promptly report safety concerns to the Department; and

5. Assist the Department in evaluating the safety and efficacy of the State demonstration project, and evaluating whether the results of the State demonstration project are consistent with the results of the C-PORT-E Study.

…

"Department" means the New Jersey [State] Department of Health [and Senior Services].

…

["Elective angioplasty demonstration project" means the demonstration project pertaining to elective angioplasty or percutaneous coronary intervention (PCI) without coronary artery bypass graft (CABG) surgical back-up on-site as part of the Atlantic C-PORT-E trial.]

"Elective" means performed on a non-emergent basis.

…

["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 a general hospital which is located in a city with a population which is greater than 50,000 (or in a city with a 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).]

"In-stent restenosis" means the recurrence of narrowing in a coronary artery that previously had been opened with a stent.

"Interventionalist" means a physician who is privileged at a participating hospital to perform PCI.

...

"[Long term] **Long-term** acute care hospital-within-a-hospital" means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 [C.F.R.] **CFR** Part 412 [et al.] that occupies space in a building also used by another hospital and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38.

"[Long term] **Long-term** acute care hospital-freestanding" means a hospital established in accordance with the standards imposed by the United States Department of Health and Human Services at 42 [C.F.R.] **CFR** Part 412 [et al.] that is a physically separate self-contained facility and is licensed as a special hospital in accordance with N.J.A.C. 8:43G-38.

...

"Participating hospital" means a hospital that is licensed to perform elective PCI in the State demonstration project.

…

"Percutaneous Coronary Intervention" or "PCI" means angioplasty or

percutaneous coronary intervention as defined at N.J.A.C. 8:33E-1.2.

…

"Primary" means performed on an emergent basis.

…

["Satellite hospital" means, for purposes of N.J.A.C. 8:33E-3.11, a general hospital that is not the inner city hospital which is the subject of an inner city cardiac demonstration project, but which shall be a general hospital within the same hospital system as the inner city hospital at issue.]

…

"State elective angioplasty demonstration project" or the "State demonstration project" means the scientific and rigorous collection and analysis of data that would expand the evidence base of the safety and efficacy outcomes of elective PCI performed in New Jersey hospitals without on-site coronary artery bypass graft (CABG) surgical back-up.

...

SUBCHAPTER 3. TYPES OF CERTIFICATE OF NEED APPLICATIONS

8:33-3.11 Demonstration and research projects

(a)-(b) (No change.)

[(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

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 CN pursuant to the expedited review process set forth in N.J.A.C. 8:33-5 and in response to a call issued by the Department. 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 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 teaching hospital that provides a comprehensive complement of invasive therapeutic cardiac services;

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 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.

(d) The Commissioner shall accept certificate of need applications for bloodless surgery demonstration projects in accordance with the provisions of the expedited review process set forth at N.J.A.C. 8:33-5.1(a) following a call for applications.

1. The Commissioner shall approve, in writing, no more than two certificate of need applications for bloodless surgery demonstration projects in any consecutive 24-month period, beginning on August 16, 1999.

2. The Commissioner shall approve each bloodless surgical demonstration project for a period of no more than 30 months from the date of notice of the written approval, but the Commissioner, in his or her discretion, may extend the date of termination of a demonstration project upon written request made by the hospital approved for the bloodless surgical demonstration project, and the extent that the utilization, staffing, outcome, policy and procedure criteria of this rule have been achieved during the course of the demonstration period.

3. An applicant for a bloodless surgery demonstration project shall:

i. Be a general hospital meeting the requirements set forth at N.J.A.C. 8:33E and 8:43G; and

ii. Have an existing invasive cardiac diagnostic service that has been in compliance with the minimum annual utilization requirements at N.J.A.C. 8:33E-1.4(b)1 and the cardiac licensing requirements at N.J.A.C. 8:43G-7 for at least the three year period prior to the date of submission of the application for the bloodless surgery demonstration project.

4. A general hospital proposing to engage in a bloodless surgery demonstration project shall submit an application to the Department demonstrating the following:

i. That the applicant's bloodless surgery demonstration program shall serve a minimum of 100 patients per year in which each procedure, if performed conventionally, would result in a blood loss of greater than or equal to 1,000 cubic centimeters;

ii. That the applicant shall have qualified staff and staffing levels for the bloodless surgery demonstration project at all times that shall promote safety, including a bloodless surgery program coordinator who shall be a graduate of an accredited school of nursing and hold a current license to practice nursing care in New Jersey, and who shall be responsible for administration of:

(1) Patient care activities;

(2) Compilation of statistical information;

(3) Marketing activities designed to promote patient access;

(4) Physician referrals;

(5) Program staffing;

(6) Maintenance of policies and procedures; and

(7) Consultation services;

iii. That the applicant's physical plant and equipment standards for the bloodless surgery demonstration project shall result in the highest level of successful bloodless surgical outcomes;

iv. The service area for the provision of the bloodless surgery demonstration project;

v. That the applicant has developed and shall implement policies and procedures for the daily operation of the bloodless surgery demonstration project addressing, at a minimum:

(1) Hospital administration and governance;

(2) Patient services;

(3) Quality improvement;

(4) Patient health care needs;

(5) Safety and infection control;

(6) Comfort and pain management;

(7) Skin integrity;

(8) Psychosocial and spiritual health;

(9) Patient and family education;

(10) Discharge planning;

(11) Technical aspects of care; and

vi. That the applicant's bloodless surgery demonstration program will perform, at a minimum, 50 percent of its annual open heart surgery cases in accordance with the definition of "bloodless surgery" at N.J.A.C. 8:33-1.3.

5. A general hospital approved for a bloodless surgical demonstration project shall submit quarterly evaluation reports to the Department for the duration of the demonstration project, with a final evaluation report immediately following the completion of the demonstration project, unless the Commissioner determines and notifies the hospital in writing that the hospital shall report more or less frequently than quarterly.

i. Each evaluation report shall include documentation of the number of bloodless surgical procedures performed by type of surgery, and success rates in terms of both morbidity and mortality.

ii. Each report shall be accompanied by supporting data.

6. The standards and conditions set forth in the Commissioner's notice of approval of a bloodless surgical demonstration project shall be the applicable licensure standards for that demonstration project until the completion of the demonstration project, but shall be in addition to, not in lieu of, the general surgery licensure standards set forth at N.J.A.C. 8:43G-34, the cardiac surgery licensure standards set forth at N.J.A.C. 8:43G-7 and other licensing standards applicable for the type of surgery performed.

i. In the event that the Commissioner shall extend the period of the demonstration project by written notice, the same standards and conditions set forth in

the initial notice of approval shall continue to apply during the duration of the extension of the demonstration project.

ii. All facilities seeking to initiate bloodless surgery demonstration projects described in this subchapter shall document compliance with all applicable requirements for cardiac surgery services and invasive therapeutic cardiac services as set forth at N.J.A.C. 8:33E, including facility and physician annual volume standards, personnel and staffing requirements. Compliance with the applicable requirements as set forth at N.J.A.C. 8:33E-2.1 through 2.14 shall be maintained throughout the period of the demonstration project and thereafter as required.

7. All facilities seeking to initiate bloodless surgery demonstration projects 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.

i. Initial licenses granted to bloodless surgery demonstration projects shall be valid for a period not to exceed 30 months from the month in which the facility initiates its bloodless surgery demonstration project.

ii. Following the expiration of the initial license, licenses for bloodless surgery demonstration projects may be renewed only upon 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. 8:43G, 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 the bloodless surgery demonstration project under this 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 demonstration program described in this subchapter shall submit to the Department, documentation of their full compliance with all standards and criteria referenced in (d)7ii above, specifically including, but not limited to, the independently audited and verified criteria specified in N.J.A.C. 8:33-3.11(d)4.

(A) Failure to submit all information/documentation required for consideration of renewal in the time and manner set forth in (d)7ii(1) above, shall, absent the express written consent of the Department, constitute a basis for denial of the request for license renewal.

(B) Following the completion of the 26th month after the initiation of services under the bloodless surgery demonstration project, documentation of compliance with the requirements of (d)7ii(1) above shall only be accepted for consideration at the express written request of the Department.

(2) Upon receipt of the documentation required for renewal as set forth in (d)7ii(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 bloodless surgery demonstration project, communicate a decision to the facility as to

whether the license to provide services approved under this bloodless surgery demonstration project will be renewed.

(3) Facilities not receiving an express written notification of the renewal of their license authorized under the bloodless surgery demonstration project described in this subchapter in accordance with (d)7ii(2) above, shall cease all such services that were initiated as a result of the bloodless demonstration project 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.

8. Notwithstanding (d)6 and 7 above, within 180 days following the promulgation of rules by the Department, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., specific to standards for bloodless surgical programs and procedures, any conditions and standards set forth in a notice of approval of a bloodless surgical demonstration project that is less stringent than, or otherwise in conflict with, the standards promulgated by the Department shall be superseded by the rules.

i. In order to maintain approval of a bloodless surgical demonstration project, each general hospital with a bloodless surgical demonstration project shall submit documentation no later than 180 days following the effective date of such rules demonstrating that its bloodless surgical demonstration project is in compliance with the new or additional standards set forth by the Department.

ii. A hospital that fails to submit documentation of its compliance with the new standards, or that otherwise fails to comply with the new or additional standards shall cease its bloodless surgical demonstration project within 30 days following the date of written notice from the Commissioner of the general hospital’s failure to comply,

except with respect to follow-up care and discharge planning for current patients participating in the bloodless surgical demonstration projects, and shall provide all necessary assistance to physicians and their patients in locating another hospital with an approved bloodless surgical program.

(e) The Commissioner shall accept certificate of need applications from general hospitals for participation in the elective angioplasty demonstration project, in accordance with the full review process at N.J.A.C. 8:33-4.1 following a call for applications.

1. The purpose of the State's participation in the Atlantic C-PORT-E trial through the approval of certificates of need to participate in the elective angioplasty demonstration project is to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty or PCI with and without on-site CABG surgical back-up.

2. The Commissioner shall approve, in writing, no more than 12 certificate of need applications for participation in the elective angioplasty demonstration project.

3. Notwithstanding the duration of demonstration projects set forth at (f)4 below, the Commissioner shall continue to issue licenses to participate in the elective angioplasty demonstration project for a period that extends to on or before December 31, 2014, which licenses are annually renewable during the period, and provided that such licenses shall be valid only during the period that cases are being entered in the Atlantic C-PORT-E registry.

i. The Department may extend the certificates of need through licensure to participate in the elective angioplasty demonstration project on an annual basis only if the Medical Director of the Atlantic C-PORT-E registry submits written notice to the Commissioner that the Atlantic C-PORT-E registry is authorized to continue patient entry in the registry.

ii. Absent a valid certificate of need and license, participating hospitals in the Atlantic C-PORT-E registry shall discontinue patient enrollment and cease performance of elective angioplasty or PCI. Certificate holders are allowed to comply with final reporting and other administrative requirements associated with participation in the Atlantic C-PORT-E registry.

iii. Prior to licensure by the Department to continue elective PCI in the Atlantic C-PORT-E registry, all elective angioplasty demonstration project hospitals shall provide written attestation to the Department that it will comply with all protocols and standards set forth in the Atlantic C-PORT-E registry Manual of Operations and Department PCI licensing standards, including, but not limited to:

(1) Agreement to abide by physician, patient and device selection criteria;

(2) Approval of the registry protocol by the demonstration project's Institutional Review Board;

(3) Agreement to comply with Atlantic C-PORT-E minimum annual facility and physician PCI volume requirements and Department annual PCI volume and licensing requirements set forth at N.J.A.C. 8:33E and 8:43G-7;

(4) Agreement to perform elective PCI only via the Atlantic C-PORT-E registry protocol and only while cases are being entered in the registry;

(5) Agreement to collect and transmit Atlantic C-PORT-E trial nine-month follow-up data and Atlantic C-PORT-E registry data in a timely fashion;

(6) Agreement to maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review;

(7) Agreement that the demonstration project hospital is willing to report elective PCI data to the Department separate from data collected as part of the registry protocol, to support the Department's ongoing monitoring of licensed cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10; and

(8) Agreement to obtain necessary informed consent for patient participation in the demonstration.

4. A licensed general hospital is eligible to submit applications for certificates of need to participate in the elective angioplasty demonstration project if the applicant hospital is not currently licensed to perform cardiac surgery; has signed one or more agreements with one or more New Jersey-licensed cardiac surgery centers indicating that the New Jersey-licensed cardiac surgery center is willing to participate in the Atlantic C-PORT-E trial, including collecting and submitting data to the principal investigator, as the center with on-site surgery to which some of the applicant hospital's patients will be randomly assigned for elective PCI; and the applicant hospital:

i. Is licensed to provide primary PCI; or

ii. Has an approved but not yet implemented certificate of need to provide primary PCI services.

5. The Department's issuance of a certificate of need to a participating hospital pursuant to this subsection is conditioned upon the following:

i. A participating hospital shall provide elective angioplasty or PCI only on patients enrolled or entered in the Atlantic C-PORT-E trial or registry.

ii. A participating hospital that discontinues its participation in the Atlantic C-PORT-E trial or registry, whether voluntarily or involuntarily, shall immediately cease performing elective angioplasty or PCI, shall notify the Department of the termination of its participation in the Atlantic C-PORT-E trial or registry and shall return the license authorizing it to participate in the elective angioplasty demonstration project to the Department within 30 days of the date that its participation ceases.

iii. All hospitals participating in the elective angioplasty demonstration project shall cease performing elective angioplasty or PCI, and shall return the demonstration project license authorizing them to participate in the elective angioplasty demonstration project to the Department on or before December 31, 2014, and the Department shall not issue amended certificates of need and licenses to the participating hospitals discontinuing their authorization to participate in the elective angioplasty demonstration project beyond December 31, 2014.

iv. Should all Atlantic C-PORT-E trial or registry enrollment conclude abruptly as a result of application of the trial's stopping rules (that is, generally, because the early evidence convincingly indicates safety problems), the State's participation in the trial or registry shall terminate, and all participating hospitals shall immediately

cease performing elective angioplasty or PCI and shall return their demonstration project license to the Department within 30 days of the date that enrollment ceases.

v. All participating hospitals shall continue to provide required documentation as required in the protocol Atlantic C-PORT-E trial and registry.

6. Applicants shall submit documentation addressing the following:

i. How the applicant will satisfy the study site inclusion criteria specified in the protocol for Atlantic C-PORT-E trial including:

(1) Capability of performing a specified minimum volume of diagnostic cardiac catheterizations per year;

(2) Agreement to complete an elective PCI development program;

(3) Agreement to abide by physician, patient and device selection criteria defined in “The Atlantic C-PORT Trial, Elective Angioplasty Study, Manual of Operations,” Version 3.0 (March 24, 2006), (Manual of Operations), as amended and supplemented;

(4) Agreement to collect and transmit study data in a timely fashion;

(5) Agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the study; and

(6) Agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review;

ii. The agreement of the applicant’s proposed participating interventional cardiologist to satisfy the following participating interventional cardiologist inclusion criteria:

(1) That the cardiologist meets and will continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6;

(2) That the cardiologist agrees to practice in accordance with the Atlantic C-PORT-E trial defined device and patient selection criteria; and

(3) That the cardiologist agrees to obtain necessary informed consent for patient participation in the demonstration including the identity and location of the participating cardiac surgery center(s) that are to receive randomized study patients;

iii. How the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which are designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations;

iv. The approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application;

v. How the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 PCI cases in year two and each year thereafter);

vi. The applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, and compliance with N.J.A.C. 8:33E-2.16(b) and 8:43G-7 as applicable;

vii. The applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the

Department's ongoing monitoring of licensed cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10; and

viii. The status of the applicant's application to participate in the elective angioplasty demonstration project, upon which acceptance issuance of a certificate of need is contingent, and proof of which acceptance the applicant shall submit to the Department.

7. The Department shall approve up to 12 applications for certificates of need to participate in the elective angioplasty demonstration project, after consideration of the documentation submitted pursuant to (e)6 above, the criteria at N.J.S.A. 26:2H-8 and the following criteria:

i. The applicant's ability to offer a high quality program;

ii. The applicant's ability to provide patient selection from among a community that is representative of the State's diverse regions and urban, suburban, and/or rural populations;

iii. The potential to increase access to care for minorities and the medically underserved by selection of the applicant; and

iv. The projected demonstration project elective PCI case volume by selection of the applicant.]

(c) The Commissioner shall accept certificate of need applications for the State demonstration project from eligible hospitals, which are those facilities licensed by the Department on (the effective date of this amendment) to participate in the Atlantic C-PORT-E registry.

1. An eligible hospital that elects to participate in the State demonstration project shall submit to the Department a completed certificate of need application under the expedited review process in accordance with N.J.A.C. 8:33-5.2, along with a non-refundable application fee in the amount of $7,500, (within 30 days of the effective date of this rule).

2. At the time of submission of a certificate of need application, an applicant hospital shall also provide the Department documentation that supports adherence within the past year to the protocol set forth in the Atlantic C-PORT-E Manual of Operations, listed below:

i. Performance of a minimum of 200 PCI cases at the participating hospital;

ii. Performance of at least 75 PCI cases per interventionalist;

iii. Patient selection protocols; and

iv. Device limitations.

3. If the Department denies an application for a certificate of need pursuant to N.J.A.C. 8:33-5.2 to participate in the State demonstration project, the applicant hospital shall cease performing elective PCI within 30 days of receipt of the letter of denial.

i. An applicant hospital that receives a letter of denial pursuant to (c)3 above has the right to appeal the Department's decision in accordance with N.J.A.C. 8:33-4.15.

4. If the Department approves an application for a certificate of need pursuant to N.J.A.C. 8:33-5.2 for participation in the State demonstration project,

an applicant hospital that obtains licensure to perform elective PCI within the State demonstration project shall:

i. Perform a minimum of 200 PCI cases per year at the participating hospital, in accordance with N.J.A.C. 8:33E-2.3(d), calculated based on the last four quarters of operation prior to the facility's licensure anniversary date;

ii. Ensure that each of its interventionalists perform at least 75 PCI cases per year per interventionalist, in accordance with N.J.A.C. 8:33E-2.3(d), calculated on a calendar-year basis;

iii. Designate for the cardiac catheterization laboratory a medical director who is licensed in New Jersey as a physician, board-certified in Interventional Cardiology by the Cardiovascular Subspecialty Board of the American Board of Internal Medicine, and responsible for maintaining compliance with, and assuring the overall integrity of, the hospital's participation in the State demonstration project;

iv. Provide support staff to assist with elective PCI in accordance with N.J.A.C. 8:33E-2.4(e) and 8:43G-7.29 and 7.30;

v. Provide registered professional nurses licensed in New Jersey who possess demonstrated competencies in hemodynamic monitoring and intra-aortic balloon pump (IABP) management;

vi. Provide cardiac catheterization laboratory technical staff who have been trained at an interventional laboratory in a cardiac surgery center, in accordance with N.J.A.C. 8:33E-2.16(b)7;

vii. Provide cardiac catheterization laboratory equipment required at N.J.A.C. 8:33E-2.16(b)8 and 8:43G-7.19;

viii. Provide primary PCI in accordance with N.J.A.C. 8:33E-2.16 and 8:43G-7, as applicable;

ix. Obtain from each enrolled patient written informed consent for participation in the State demonstration project as set forth at (c)5 below;

x. Comply with patient selection protocols at (c)9 and 10 below;

xi. Comply with exclusionary criteria for patients with high procedural risk at (c)11 below;

xii. Comply with device limitations at (c)12 below;

xiii. Obtain written approval from the participant hospital's Institutional Review Board (IRB) of the State demonstration project protocols prior to licensure for elective PCI;

xiv. Report to the Data Monitor all available patient data and any additional information as requested by the Department and/or the Data Monitor to assess the safety and efficacy outcomes of the State demonstration project;

xv. Maintain, as part of the participating hospital's quality assessment program, an ongoing program of outcomes analysis and periodic case review;

xvi. Maintain the equivalent of one full-time employee (FTE) responsible for the timely and accurate collection and submission of data on each elective PCI case within 24 hours of procedure completion to the Data Monitor, and to the Department in accordance with N.J.A.C. 8:33E-1.9 and 2.10;

xvii. Report adverse events, including death, the need for emergency cardiac surgery, or other events as may be identified by the Data Monitor, within one hour of occurrence to the Data Monitor; and

xviii. Compensate the Data Monitor for costs associated with reviewing the participating hospital's performance in the State demonstration project as set forth at N.J.A.C. 8:33-1.3.

5. Participating hospitals shall ensure that, before the commencement of diagnostic cardiac catheterization, each enrolled patient provides written informed consent to participate in the State demonstration project after receiving the following information and an opportunity to review and consider such information:

i. Elective PCI without surgery on site is not permitted in New Jersey except as part of the State demonstration project;

ii. Elective PCI is performed in hospitals with surgery on site because emergency cardiac surgery may be required for procedure-related complications;

iii. If an enrolled patient requires emergency cardiac surgery, the participating hospital has a plan in place for emergency transfer;

iv. An enrolled patient may not be eligible for elective PCI at a participating hospital if the enrolled patient needs cardiac surgery, meets the exclusionary criteria for patients with high procedural risk for elective PCI at (c)11 below, or requires treatment that is not available at the participating hospital;

v. For ineligibility based on the reasons cited in (c)5iv above, a participating hospital would transfer an enrolled patient to a licensed cardiac surgery center for appropriate care; and

vi. A participating hospital is required to share an enrolled patient's medical information with the Data Monitor and the Department, who shall treat such information confidentially.

6. The participating hospital's IRB shall approve the individual that the hospital designates to provide information to, and obtain written informed consent from, enrolled patients.

7. Each participating hospital shall have a collaboration agreement with a New Jersey cardiac surgery center located, in the following order of preference:

i. In the same municipality as that in which the applicant is located;

ii. In the same county as that in which the applicant is located; or

iii. In a county that is contiguous to the county in which the applicant is located.

8. The documented collaboration agreement required pursuant to (c)7 above shall include the following:

i. Written protocols for enrolled patients who require transfer to, and receipt at, a cardiac surgery center's operating room within one hour of the determination of the need for such transfer, including the emergency transport of patients who require an IABP;

ii. Regular consultation between the two hospitals on individual cases, including use of technology to share case information in a rapid manner; and

iii. Evidence of adequate cardiac surgery on-call backup.

9. Participating hospitals shall limit enrollment in the State demonstration project to those inpatients and outpatients undergoing diagnostic cardiac catheterization for suspected coronary artery disease who do not exhibit any of the following exclusionary criteria:

i. Inability to give informed consent;

ii. ST-segment elevation myocardial infarction;

iii. Pregnancy; or

iv. Refusal to participate in the State demonstration project.

10. Following diagnostic cardiac catheterization and prior to performing PCI services, participating hospitals shall not perform PCI on enrolled patients who demonstrate the following:

i. No need for PCI;

ii. Need for coronary artery bypass surgery;

iii. High procedural risk as defined at (c)11 below; or

iv. High likelihood of requiring a device that is not available at the participating hospital as defined at (c)12 below.

11. Participating hospitals shall not perform elective PCI on enrolled patients who, upon completion of a diagnostic cardiac catheterization, exhibit any of the following criteria for high procedural risk:

i. Unprotected left main coronary artery;

ii. Left circulation lesion in the presence of greater than 70 percent unprotected left main coronary artery lesion; or

iii. Poor left ventricular function with an ejection fraction of 20 percent or less, and need for PCI in a vessel supplying to significant myocardium.

12. Participating hospitals shall not use the following devices in PCI services:

i. Any atherectomy device; or

ii. Cutting balloons, except within stents for in-stent restenosis.

13. Participating hospitals licensed to provide elective PCI under the State demonstration project shall comply with N.J.A.C. 8:33E-2.3(d), as applicable, this chapter, and any conditions imposed in its certificate of need as a condition of licensure.

14. Participating hospitals that discontinue participation in the State demonstration project, whether voluntarily or involuntarily, shall immediately cease performing elective PCI and, within 30 days of discontinuation, shall return to the Department the license authorizing participation in the State demonstration project.

15. Upon termination of the State demonstration project, all participating hospitals shall immediately cease performing elective PCI and shall return the demonstration project license to the Department.

16. Notwithstanding (d)4 below, the State demonstration project will last no more than 18 months, the State demonstration project shall be in effect until the

Department promulgates new rules at N.J.A.C. 8:33E for elective angioplasty without cardiac surgery backup and issues licenses under those rules, and establishes the following:

i. Minimum standards by which hospitals may perform elective PCI without cardiac surgery backup.

ii. A Statewide certificate of need call for a limited number of hospitals to provide elective PCI without cardiac surgery on-site under the full review process.

[(f)] **(d)** (No change in text.)

SUBCHAPTER 4. THE REVIEW PROCESS

8:33-4.3 Submission of applications

(a) [Thirty-five] **Prospective applicants may obtain a certificate of need application for full review (comprised of forms CN-1, 3, and 4) on the Department's website at www.nj.gov/health/forms and shall submit the completed application using electronic media and 35 paper** copies of the application [shall be submitted] to:

Office of Certificate of Need and Healthcare Facility Licensure

New Jersey [State] Department of Health [and Senior Services]

PO Box 358

Trenton, [New Jersey] **NJ** 08625-0358

(609) 292-6552 [and] **or** 292-7228

(b) (No change.)

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.2 Process

(a)-(d) (No change.)

(e) [Certificate of need application forms for expedited review may be obtained from the Department at the address listed below. Applicants should contact staff of the Office of Certificate of Need and Healthcare Facility Licensure before filing an application to be certain that they have a copy of the most recent version of the Department's application. An original and nine copies of the application shall be filed with] **Prospective applicants may obtain a certificate of need application for expedited review (form CN-19) on the Department's website at www.nj.gov/health/forms and shall submit the completed application using electronic media and 10 paper copies of the application to**:

Office of Certificate of Need and Healthcare Facility Licensure

New Jersey [State] Department of Health [and Senior Services]

PO Box 358

Trenton, [New Jersey] **NJ** 08625-0358

(609) 292-6552[,] or 292-7228

(f) (No change.)