HEALTH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Proposed Amendments: N.J.A.C. 8:33-3.11(e)

Certificate of Need: Application and Review Process

Types of Certificate of Need Applications: Demonstration and Research Projects

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


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

Proposal Number: PRN 2012-

Submit written comments by                         , 2012 to:

Walter C. Kowalski, Acting Director
Office of Legal and Regulatory Compliance
New Jersey Department of Health
PO Box 360
Trenton, New Jersey 08625-0360

The agency proposal follows:

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the New Jersey Register or New Jersey Administrative Code. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.
Summary

The Department of Health (Department) proposes amendments to extend the licensure of elective angioplasty demonstration projects in order to continue participation of New Jersey licensed general hospitals in the Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-PORT-E) registry. The proposed licensure extension would permit existing demonstration projects to continue to provide elective PCI services while providing sufficient time for the Department to seek to establish future statewide policy regarding the provision of elective angioplasty at hospitals with and without on-site cardiac surgery services. The Atlantic C-PORT-E registry continues to be a multi-state repository of patient-specific elective angioplasty or percutaneous coronary intervention (PCI) data in hospital settings that are without on-site cardiac surgery.

The proposed amendments would allow qualified elective angioplasty demonstration projects to continue to provide elective PCI as participants in the Atlantic C-PORT-E registry, which was initiated following the suspension of the Atlantic C-PORT-E research trial patient enrollment on March 31, 2011 (that is, the date the research trial had reached its patient enrollment target of 18,360 patients).

The published trial results “found that PCI performed at hospitals without on-site cardiac surgery was non-inferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months.” The trial results, however, were conducted under rigid research protocols that limited such things as potential candidate risk factors and intervention devices and maximized clinical outcome measures, such as annual facility volume, clinician experience and competence.

Under the current demonstration project rules set forth in this chapter at N.J.A.C. 8:33-3.11(e), the State’s eleven elective angioplasty demonstration projects would be required to cease elective angioplasty services on or before February 9, 2013. In order to minimize the potential adverse impact of the abrupt cessation of elective angioplasty services at these demonstration project sites, while the Department evaluates future statewide elective angioplasty policy, the Department is proposing amendments that would extend the licensing period of the elective angioplasty demonstration projects that remain in compliance with state licensing requirements until December 31, 2014. The proposed extension would permit Department staff, in consultation with the Cardiovascular Health Advisory Panel (CHAP) in its role as an advisory body to the Department, to fully review the findings of the research trial and recommend options that would provide clinically sound Statewide policy in this area. In conjunction with this extensive policy review, the Commissioner’s Cardiovascular Health Advisory Panel (CHAP) and the New Jersey Chapter of the American College of Cardiology co-sponsored a Statewide
Symposium ("PCI Without Cardiac Surgery On Site – An Expert Panel Review") on November 27, 2012, which included Dr. Aversano and other national experts. Subsequently, the State Health Planning Board (SHPB) will conduct regional hearings on elective angioplasty to allow for a public and transparent discussion.

A summary of the proposed amendments follows:

Proposed amendments at N.J.A.C. 8:33-3.11(e)3 and 5iii would allow hospitals previously granted certificates of need and which are in compliance with licensing requirements as elective angioplasty demonstration projects in the Atlantic C-PORT-E trial to continue participation in the Atlantic C-PORT-E registry until December 31, 2014. Further amendments set forth at N.J.A.C. 8:33-3.11(e) would delete references to the need to amend the demonstration project hospital’s certificate of need and license in order to remove the authorization to perform elective angioplasty, since each elective angioplasty demonstration project is issued a separate annual license for the elective angioplasty service with distinct effective and expiration dates that do not appear on each demonstration project’s general hospital license. The Department performs an annual service-specific licensing review of each demonstration project’s performance to ensure compliance with state licensing requirements and Atlantic C-PORT-E protocols.

Proposed amendments at N.J.A.C. 8:33-3.11(e)3 and 5 would provide that licensing rather than certificate of need action will be taken to evaluate each demonstration project’s annual compliance with elective angioplasty demonstration project performance requirements. The separate and distinct elective angioplasty
demonstration project license, which has been evaluated each year by the Department on an individual demonstration project basis based on its respective anniversary date, would be “discontinued” rather than “deleted” as described in the current text on or before December 31, 2014. The Department anticipates that a statewide elective angioplasty policy will be in place at that time.

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. 1:30-3.1 and 3.2.

**Social Impact**

N.J.S.A. 26:2H-1 et seq., as amended, recognizes as the "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."

The proposed amendments would continue to authorize the eleven general hospitals that have received certificate of need approval and licensure as elective angioplasty demonstration projects and are in compliance with licensing requirements to continue participation in the Atlantic C-PORT-E registry, through the scientifically rigorous collection and analysis of data that would contribute to the national evidence base on the issue of the comparative safety and efficacy of elective angioplasty in hospitals without on-site coronary artery bypass graft (CABG) surgery. Clinical advances in coronary intervention techniques over the years have continued to greatly reduce the rate of PCI complications requiring emergency surgery. More
recently, with improvements in catheter and device design, the advent of coronary stents and improved techniques, and the monitoring of antiplatelet and anticoagulation regimens, PCI has become increasingly safe and effective, with emergency CABG rates ranging from two percent to less than 0.4 percent (Levine, et al., Circulation, "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions," November 7, 2011).

The results of the Atlantic C-PORT-E research trial concluded that PCI performed at hospitals without on-site cardiac surgery was non-inferior to PCI performed at hospitals with on-site cardiac surgery with respect to six-month mortality and major adverse cardiac events at 9-months (Aversano, et al., New England Journal of Medicine, May 10, 2012). It is important to emphasize the fact that the research trial protocols under which the trial was conducted were necessarily rigorous in order to minimize patient risk. It is therefore incumbent upon the Department to structure future policy regarding elective PCI that mimics as much as possible the safeguards that were in place for the Atlantic C-PORT-E trial and registry.

The proposed amendments would ensure that New Jersey hospitals that participate in the elective angioplasty demonstration projects continue to comply with Department and Atlantic C-PORT-E trial and registry facility and physician volume requirements and Atlantic C-PORT-E trial and registry informed consent, patient
selection, device selection criteria, and data reporting standards. Strict compliance with these requirements would continue to provide the scientific performance data that is necessary to evaluate and compare the safety and efficacy of elective angioplasty at hospitals without on-site cardiac surgery backup.

The proposed amendments would continue the criteria and standards to ensure patient safety. The Atlantic C-PORT-E registry’s Manual of Operations would continue to require hospital participants to maintain institutional review board approval, the need for informed consent for every PCI patient entered in the Atlantic C-PORT-E registry, as well as adherence to strict Atlantic C-PORT-E trial and registry patient selection criteria and facility and interventional cardiologist inclusion criteria. Most importantly, the proposed amendments would continue to require hospitals participating in the elective angioplasty demonstration project to comply with stricter performance standards and oversight than other providers of elective PCI services in New Jersey (that is, cardiac surgery centers).

The proposed amendments would ensure that those hospitals that participate in the elective angioplasty demonstration project going forward would continue to adhere to the performance standards of the Department and the Atlantic C-PORT-E registry. The proposed amendments would also provide sufficient time for the Department to carefully evaluate the findings of the Atlantic C-PORT-E research study, to gather additional evidence-based scientific information, assess the impact of the elective angioplasty demonstration projects on existing cardiac surgery centers,
and to solicit feedback from stakeholders including the medical, quality care and emergency medical service communities and the public at large.

Economic Impact

The proposed amendments would continue to allow the successful applicants, which may have incurred costs associated with renovating or constructing physical space to provide PCI services, and employing additional staff to provide the services and implement administrative activities associated with the Atlantic C-PORT-E registry, to continue to be licensed to provide elective angioplasty. These costs would continue to depend on facility-specific variations in existing physical and staff resources and corresponding needs to augment those resources to comply with Department and Atlantic C-PORT-E standards. The Department anticipates that it is more likely that facilities would conduct reporting and other administrative requirements associated with participation in the Atlantic C-PORT-E registry using existing staff resources.

Those successful applicants who have obtained certificates of need to provide elective angioplasty demonstration projects may continue to realize increased patient censuses and reimbursement levels from the addition of elective PCI. Hospitals with cardiac surgery facilities may have realized a corresponding decrease in patient censuses and reimbursement levels.

Federal Standards Statement

The Department is not proposing the proposed amendments under the authority of or to implement, comply with, or participate in any program established
under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

**Jobs Impact**

As discussed in the Economic Impact above, facilities that participate in the Atlantic C-PORT-E registry may need to continue to supplement existing staff depending on their existing resources as necessary to comply with reporting and other administrative requirements associated with the registry, but the Department anticipates that it is more likely that facilities would fulfill these requirements using existing staff resources.

As discussed in the Economic Impact above, hospitals with cardiac surgery facilities may continue to realize a decrease in patient census and reimbursement levels which would have already resulted in some job losses related to providing this procedure in a reduced capacity.

Subject to the discussion above, the Department does not anticipate that the proposed amendments would result in the creation or loss of any jobs.

**Agriculture Industry Impact**

The proposed amendments would have no impact upon the agriculture industry in New Jersey.

**Regulatory Flexibility Statement**

The proposed amendments would continue to impose reporting, recordkeeping and compliance requirements only on New Jersey licensed general hospitals, none of which is a "small business" within the meaning of the Regulatory
Flexibility Act, N.J.S.A. 52:14B-16 et seq., as each employs more than 100 people full-time. Therefore, a regulatory flexibility analysis is unnecessary.

**Smart Growth Impact**

The proposed amendments would have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

**Full text** of the proposal follows (additions indicated in boldface *thus*; deletions indicated in brackets [thus]):

8:33-3.11 Demonstration and research projects

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

(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. - 2. (No change.)

3. Notwithstanding the duration of demonstration projects set forth at (f)4 below, the Commissioner shall [issue certificates of need] *continue to issue licenses* to participate in the elective angioplasty demonstration project for a period that extends [for nine months following the publication of the trial results in a peer-reviewed journal] *to on or before December 31, 2014*, which [certificates of need] **licenses** are annually renewable during the period, and provided that such
[certificates of need] 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. (No change.)

4. (No change.)

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

   i. (No change.)

   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 [certificate of need] license authorizing it to participate in the elective angioplasty
demonstration project to the Department within 30 days of the date that its participation ceases[, and the Department shall issue the hospital an amended certificate of need deleting its authorization to participate in the elective angioplasty demonstration project].

iii. [When the Atlantic C-PORT-E trial publishes the trial results in a peer-reviewed journal, all] All hospitals participating in the elective angioplasty demonstration project shall cease performing elective angioplasty or PCI, and shall return the [certificates of need] demonstration project license authorizing them to participate in the elective angioplasty demonstration project to the Department [within nine months of the date of publication of the trial results,] on or before December 31, 2014 and the Department shall not issue amended certificates of need and licenses to the participating hospitals [deleting] 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 [certificate of need] demonstration project license to the Department within 30 days of the date that enrollment ceases[, and the Department shall issue each hospital an amended certificate of need deleting its authorization to participate in the elective angioplasty
demonstration project].

v. (No change.)

6. - 7. (No change.)

(f) (No change.)