HEALTH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Certificate of Need: Application and Review Process

Types of Certificate of Need Applications: Demonstration and Research Projects

Adopted Amendments: N.J.A.C. 8:33-3.11

Proposed: February 4, 2013 at 45 N.J.R. 191(a)

Adopted by: Mary E. O’Dowd, MPH, Commissioner, Department of Health (with the approval of the Health Care Administration Board).

Filed: as R. 2013 without change.


Effective Date: Expiration Date:

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received written comments from a total of five commenters during the 60-day public comment period which ended on April 5, 2013. Comments were received from the following:

1. Catherine Yaxley, Vice President, Planning and Government Affairs, Holy Name Medical Center, Teaneck, New Jersey;

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2. Richard P. Miller, President and Chief Executive Officer, Virtua Health, Inc., Marlton, New Jersey;
3. Jillian Hudspeth, Director of Government and Community Affairs, JFK Health System, Edison, New Jersey;
4. Gary S. Horan, FACHE, President and Chief Executive Officer, Trinitas Health and Regional Medical Center, Elizabeth, New Jersey;
5. John P. Sheridan, Jr., President and Chief Executive Officer, Cooper Health System, Camden, New Jersey.

The number in parenthesis after each comment identifies the respective commenter(s) listed above.

COMMENT: A commenter, representing an elective angioplasty demonstration project hospital, expressed “strong support of the proposed amendments to N.J.A.C. 8:33-3.11, which permit qualified hospitals currently participating in the elective coronary angioplasty (C-PORT-E) demonstration project to continue their participation while allowing the Department sufficient time to establish Statewide policy regarding the provision of elective coronary angioplasty at hospitals with and without co-located cardiac surgery services.” The commenter views the proposed amendments as a “logical next step in the process to formulate policy regarding evidence-based medicine” and expressed appreciation for “the Department’s understanding of the adverse impact that would result from the abrupt
cessation of elective PCI at C-PORT-E hospitals if the licenses weren’t extended during the evaluation period.” (1)

RESPONSE: The Department is thankful for the commenter’s strong support of the proposal.

COMMENT: A commenter, representing an organization of four hospitals, one of which is an elective angioplasty demonstration project hospital, expressed strong support of the proposed amendments to N.J.A.C. 8:33-3.11. The commenter reviewed the history of the Johns Hopkins Atlantic C-PORT-E trial and characterized it as “an important study that generated data needed to determine the difference in outcomes of elective percutaneous coronary intervention (‘PCI’) performed at hospitals that have cardiac surgery back-up on-site and those that have off-site surgical backup.” The commenter maintains that the Department’s decision in 2005 to allow a limited number of New Jersey hospitals to participate in the Atlantic C-PORT-E trial “has been rewarded by some seven years of successful operations of PCI programs in the participating hospitals.” Rather than requiring the demonstration project hospitals to discontinue elective PCI services on or before February 13, 2013, the commenter noted that the Department’s proposal would permit qualified hospitals currently participating in the elective coronary angioplasty (C-PORT-E) demonstration project to continue their participation while allowing the Department sufficient time to establish Statewide policy regarding the provision of elective coronary angioplasty at hospitals with and without on-site cardiac surgery services.
Furthermore, the commenter stated that in its view the proposed amendments safely serve the Department’s goal of contributing to published data regarding the performance of elective angioplasty without cardiac surgery on-site. The commenter also noted that the new amendments would allow the Department sufficient time to assess published C-PORT-E study data without requiring the unnecessary termination of elective PCI at C-PORT-E hospitals and that there are several economic factors that weigh in favor of continuing the elective angioplasty demonstration project until a responsible and reasonable policy is established. The first economic factor is that elective PCI programs support the primary or emergency PCI service through increased procedure volume that serves to maintain a high standard of care. In addition, the investment in equipment and physician and professional staff would be jeopardized by the potential abrupt cessation of elective PCI services that could conceivably be dismantled only to be potentially reactivated by an impending future policy decision.

The commenter also emphasized that the Department’s actions in allowing the elective angioplasty demonstration projects to continue performing elective PCI under defined circumstances in the Atlantic C-PORT-E registry was consistent with the decisions of Ohio, Maryland and Pennsylvania and also consistent with the broader policy nationally as 28 states now permit elective angioplasty to be performed without on-site cardiac surgical back-up. Finally, the commenter suggests what it characterizes as a non-substantive amendment to the hospital licensing rules at
N.J.A.C. 8:43G-7-28(a) that adds the phrase “and the licensing standards of N.J.A.C. 8:33-3.11 have been met” to that subsection. (2)

RESPONSE: The Department appreciates the commenter’s strong support of the proposed amendments but respectfully disagrees with the commenter’s suggestion of the need to amend the hospital licensing standard to indicate the need for the elective angioplasty demonstration projects to adhere to the licensing standards set forth in this section of Chapter 33. All certificate of need (CN) approved elective angioplasty demonstration projects were granted approval with conditions which require continuous compliance with licensing requirements. In accordance with N.J.A.C. 8:33-4.16(b), any conditions placed on CN approvals “shall become part of the licensing requirements of the approved facility” and, if not in compliance, “may result in licensure action by the Department.” In short, there is no need for the clarifying language suggested by the commenter and therefore no changes to the proposal will be made in response to the comment.

COMMENT: A commenter, representing an elective angioplasty demonstration project hospital, expressed strong support of the proposed amendments to N.J.A.C. 8:33-3.11, which permits qualified hospitals currently participating in the elective coronary angioplasty (C-PORT-E) demonstration project to continue their participation until December 31, 2014. The commenter states that the hospital was awarded a CN as an elective angioplasty demonstration project on November 10, 2008 and is one of eleven demonstration projects currently licensed by the Department. The commenter agrees with the Department that the proposal...
would minimize the potential adverse impact of the abrupt cessation of elective angioplasty services at the demonstration project sites while allowing the Department, in consultation with the Cardiovascular Health Advisory Panel (CHAP), to fully review the research findings of the Atlantic C-PORT-E trial.

The commenter supports the proposed licensing extension which in its view continues essential cardiac services under appropriate patient safety protocols as set forth in the Atlantic C-PORT-E Study Manual. The commenter states that the Manual explains that the Study “is designed as a real world study, but is balanced by the goal of minimizing the potential for harm.” The study’s safety features include the exclusion of high risk patients, devices associated with high complication rates, and the adoption of American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI) minimum interventional case volume requirements for all participating practitioners and institutions. The commenter also indicated that the Study’s Manual of Operations provides for primary and elective PCI development and training programs and requires continuing education programs in these areas including competency maintenance requirements.

The commenter also stresses operational and economic factors that support the proposed licensing extension. The first economic factor is that elective PCI programs support the primary or emergency PCI service through increased procedure volume that serves to maintain a high standard of care. The Department has emphasized the importance of providing primary angioplasty at qualifying
community hospitals for many years and the extension of the elective angioplasty licenses at the demonstration project hospitals “benefits primary PCI programs by increasing the volume of cases seen by the primary PCI team, which corresponds directly to better quality of care for patients.” An additional economic factor involves the investment in equipment and physician and professional staff at demonstration project hospitals which would be jeopardized by the premature abrupt cessation of elective PCI services that could conceivably be dismantled only to be potentially reactivated by a subsequent favorable elective PCI policy decision. Such a situation would result not only in a significant economic loss, but an equally significant loss of professional expertise and clinical knowledge to the demonstration project hospitals.

(3)
RESPONSE: The Department appreciates the commenter’s strong support of the proposed amendments.

COMMENT: A commenter, representing an elective angioplasty demonstration project hospital, expressed support of the proposed amendments to N.J.A.C. 8:33-3.11, which permit qualified hospitals currently participating in the elective coronary angioplasty (C-PORT-E) demonstration project to continue their participation until December 31, 2014. The commenter expressed happiness but not surprise to learn that the Atlantic C-PORT-E study “found elective angioplasty with off-site cardiac surgery to be non-inferior to elective angioplasty performed at cardiac surgery centers.” The commenter applauds the Department’s decision to continue licensing the elective angioplasty demonstration projects through December 31,
2014, “while working with the hospital community to develop a regulatory framework that duplicates as much as possible the C-PORT-E research protocols that supported patient safety and quality clinical outcomes.” The commenter stated that it looked forward “to working with the Department in the coming months to ensure the continuation of elective angioplasty at New Jersey’s non-cardiac surgery C-PORT centers.” (4)

RESPONSE: The Department appreciates the commenter’s support of the proposed amendments.

COMMENT: A commenter, representing a cardiac surgery center, expressed opposition to the proposal, stating that “[t]he Department should not grant this lengthy extension.” The commenter listed a number of concerns about the proposed continuation of the elective angioplasty demonstration project licenses. The first concern was that of patient safety. The commenter stated that New Jersey “continues to disregard the recommendations of the [ACC/AHA/SCAI], none of whom endorse elective angioplasty without on-site cardiac surgery”. The second concern expressed by the commenter was that of quality. The commenter stated that by “diluting the volume of interventional cardiac procedures at New Jersey’s cardiac surgery centers, New Jersey is at risk for developing into a low volume, low quality cardiac delivery system;….” The third concern expressed by the commenter concerned the financial impact on urban safety net hospitals. The commenter stated that the proposed licensing extension “will adversely impact existing urban safety net hospitals by siphoning volume and, particularly, cases with better payers, magnifying

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substantial economic disparities between the safety net hospitals, who provide in excess of 70% of NJ’s charity care and Medicaid services, and their suburban counterparts, who do not.” The commenter considers this a subversion of a longstanding policy of locating interventional cardiology licenses at urban hospitals in order “to level the playing field;… .” A final concern expressed by the commenter involved the financial impact on health care costs. The commenter stated that the 17 licensed cardiac surgery centers could already serve the needs of New Jersey residents without incurring the additional costs associated with the development of new non-surgery center interventional programs that can only increase the cost per case.

Furthermore, the commenter considers the issues that it has raised to be serious, but not new issues. The issues have been raised throughout the demonstration project process and the commenter believes that there is no reason why the Department should be taking up to nearly another two years to resolve the issues surrounding elective angioplasty and potentially expose the citizens of this State to adverse safety, quality, and fiscal consequences. (5)

RESPONSE: The Department disagrees with the concerns raised by the commenter in opposing the proposal. The Department does agree with the commenter that the issues that are raised are serious concerns that are not new. These concerns have been addressed, however, each time that they have been raised throughout the elective angioplasty demonstration project process. The Department views the concerns raised by the commenter as continuing efforts to re-
litigate issues of safety and efficacy and the appropriateness of the Department’s
determination to participate in the Atlantic C-PORT-E trial. The Department already
addressed these matters in response to objections to the Department’s original
promulgation of rules allowing the Department to participate in the Atlantic C-PORT-E
demonstration project. 39 N.J.R. 3462(a) (August 30, 2007), 39 N.J.R. 5316(b)
(December 17, 2007), upheld by Cooper Univ. Hosp. v, Jacobs, N.J. Superior Court,
(September 10, 2009), and see related opinion at Cooper Univ. Hosp. v. Howard,
LEXIS 874 (April 11, 2011) (upholding award of certificate of need pursuant to
demonstration project rules). The Department incorporates herein by reference its
responses to those objections and the opinions of the New Jersey Superior Court,
Appellate Division, with respect to these issues.

The proposal Summary and the Department’s responses to previous com-
ments, above, articulate the reasons and need for the Department to continue the
State’s participation in the C-PORT-E trial and registry. As the Department stated in
the proposal’s Social Impact statement (45 N.J.R. 192):

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 Atlantic C-PORT-E Manual of Operations establishes patient and device selection criteria and N.J.A.C. 8:33-3.11 has incorporated these criteria as a condition of participation. N.J.A.C. 8:33E-2.3(d)1 and 2 require all facilities in the State performing elective PCI pursuant to a certificate of need (CN), regardless of whether they are trial participants, to maintain a volume of at least 200 total PCI cases per facility. This figure is identical to the volume standard of the Atlantic C-PORT-E Manual of Operations. The Atlantic C-PORT-E Manual of Operations and N.J.A.C. 8:33E-2.3(d)5 both require physicians performing PCI to maintain annual volumes of 75 cases per year. Notably, the Department uses these criterion in determining whether to authorize facilities to participate in the demonstration projects but does not use this minimum physician volume standard in evaluating licensure compliance of cardiac surgery centers. Thus, New Jersey Atlantic C-PORT-E trial/registry participants already meet a more stringent standard with respect to physician minimum annual vol-
umes than the standard facilities that have on-site cardiac surgery backup are required to meet.

Furthermore, as part of its existing oversight of cardiac services Statewide, the Department annually evaluates all facilities in the State providing cardiac services, regardless of whether they are participants in the registry, for conformance with licensure standards and performance measures. During this rigorous evaluation process, which is articulated in the rules of the Department at Title 8 of the New Jersey Administrative Code, the Department reviews facility and physician volumes and, as necessary, requires nonconforming facilities to submit plans of correction for violations. The Department also implements on-site program evaluation by independent reviewers in the event of continued non-compliance. Habitual licensure violations require a comprehensive review by the Society for Cardiovascular Angiography and Interventions (SCAI). The Department has taken and continues to take its responsibility to ensure patient safety very seriously.

With respect to the commenter’s concern over the negative financial impact of the state’s elective angioplasty demonstration projects on “urban safety net hospitals,” which presumably includes the commenter’s institution among other existing cardiac surgery centers, the Department monitors the volume of cardiac catheterization, primary and elective angioplasty, and cardiac surgery cases being performed at all licensed cardiac service providers in the State on an annual basis as a routine component of its licensing responsibility. While statewide growth in coronary angioplasty volume peaked in 2010 (26,642 total PCI cases), the total
number of PCI cases performed statewide has not greatly diminished in the past two years (-3.8% from 2010-2012) with many of the state’s “urban safety net hospitals” performing from five to more than ten times the minimum annual licensing requirement of 200 PCIs. Perhaps more importantly, the annual volume at the surgery center represented by the commenter has maintained its PCI volume during this period (952 PCI cases in 2010, 958 PCI cases in 2012) and no cardiac surgery center to date has failed to achieve the minimum annual PCI caseload necessary to maintain quality and presumably financial solvency. It should also be emphasized that several of the elective angioplasty demonstration project hospitals are located in urban settings and are providing improved access to interventional cardiology services for medically underserved and Medicaid populations in their respective service areas. The financial impact on health care costs is not only affected by the volume of cases performed at a facility, it is also impacted by extended delays in accessing treatment that lead to lengthier inpatient stays and transfer costs that are diminished by improved availability of services.

The Department also disagrees with the commenter’s assertion that the proposed amendment would have an overall negative impact on patient outcomes. Patient safety has been the primary concern of the Department whenever it has exercised its regulatory authority on the health care industry. This has been particularly true in the area of cardiovascular disease, where a succession of consultants, ad hoc and standing committees of experts and dedicated staff have combined to promulgate cardiac service certificate of need (CN) and licensing rules
that have maintained consistency with clinical cardiac care despite unprecedented changes in clinical practice.

For the past decade, the Department has required all of its licensed cardiac catheterization/intervention (PCI) and cardiac surgery programs to provide considerable performance data in the interest of patient safety. These reporting requirements have become highly sophisticated over the years to include a cardiac surgery report card and the introduction, in 2007, of a robust cardiac catheterization and PCI database patterned after the American College of Cardiology’s National Cardiovascular Data Registry (NCDR).

Pursuant to N.J.A.C. 8:43E and other laws, the Department is authorized to impose penalties and sanctions on facilities that fail to report required data. There have been few problems with reporting over the years despite the increased demands placed on facilities to provide patient-specific data for report card purposes. The Department considers its current patient safeguards to be appropriate for all patients in the State’s cardiac facilities, regardless of whether patients elect to enroll in the Atlantic C-PORT-E trial.

With respect to the commenters statement that the proposed amendment would be contrary to the position statements of the American College of Cardiology/American Heart Association (ACC/AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI), the Department considers its policy to permit New Jersey participation in the Atlantic C-PORT-E trial/registry as supportive of the positions taken by these organizations, which hold that more data is needed to assess

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whether elective PCI may be safely performed at hospitals without cardiac surgery on-site. The Department’s decision to allow New Jersey participation in the multi-state Atlantic C-PORT-E’s rigorous research study and registry has contributed significantly to the clinical data necessary to permit informed, evidence-based decisions regarding elective angioplasty service delivery.

With respect to the commenter’s concern over the length of time needed to establish elective angioplasty policy, the Department again addressed this issue in its proposal, stating that 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. The Department’s thorough review process has included a well-attended symposium on elective angioplasty with and without on-site cardiac surgery, conducted under the auspices of the Commissioner’s Cardiovascular Health Advisory Panel (CHAP) and the New Jersey Chapter of the American College of Cardiology (NJACC), which was held on November 27, 2012. The Department, in conjunction with the State Health Planning Board (SHPB), is also in the process of conducting a series of five regional public hearings on the issue, which will culminate in the development of statewide cardiac services and elective angioplasty policy that the Department will propose as new rules through the administrative rule-making process. The Department will
therefore make no changes to the proposal in response to the concerns raised by the commenter.

**Federal Standards Statement**

The Department is not adopting 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.

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