

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

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

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

Proposed: February 2, 2015, at 47 N.J.R. 319(a).

Adopted: June 18, 2015, by Mary E. O'Dowd, M.P.H., Commissioner, Department of Health (with the approval of the Health Care Administration Board).

Filed: June 18, 2015, as R.2015 d.115, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

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

Effective Dates: June 18, 2015, Readoption;
August 17, 2015, Adopted Amendments, Repeals, and New Rules.

Expiration Date: June 18, 2022.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received timely comments from the following commenters during the 60-day public comment period, which ended on April 3, 2015:

1. Ms. Corrine Orlando, American Heart Association, Robbinsville, NJ;
2. Robert Iannaccone, Senior Vice President of Cardiac Services, Barnabas Health, West Orange, NJ;

3. Steven G. Littleton, Executive Vice President, Meridian Health, and President, Meridian Hospitals Corporation, Neptune, NJ;
4. Paul E. Minnick, RN, MSN, NEA-BC, Chief Operating Officer, CarePoint Health, Bayonne Medical Center, Bayonne, NJ;
5. Marie T. Duffy, Chief Operating Officer, CarePoint Health, Christ Hospital, Jersey City, NJ;
6. Adam Beder, Vice President, Government Affairs, JFK Health, Edison, NJ;
7. Michael Antoniadis, MPA, Executive Vice President and Chief Operating Officer, Robert Wood Johnson University Hospital—New Brunswick and Somerset Campuses, New Brunswick, NJ;
8. Nancy DiLiegro, PhD, FACHE, Vice President, Clinical Operations and Physician Services, Chief Clinical Officer, Trinitas Regional Medical Center, Elizabeth, NJ;
9. Richard P. Miller, President and Chief Executive Officer, Virtua Health, Inc., Marlton, NJ;
10. Susan Bonfield, General Counsel, Vice President, Legal and Regulatory Affairs, Deborah Heart and Lung Center, Browns Mills, NJ;
11. Robert C. Garrett, President and Chief Executive Officer, Hackensack University Health Network and Hackensack University Medical Center, Hackensack, NJ, and John A. Fromhold, FACHE, Chief Executive Officer, Hackensack University Medical Center—Mountainside, Mountainside, NJ;
12. Robert P. Wise, FACHE, President and Chief Executive Officer, Hunterdon Healthcare, Flemington, NJ;

13. John A. DiAngelo, President and Chief Executive Officer, and M. Todd Way, Executive Vice President, Operations, Inspira Health Network, Mullica Hill, NJ;

14. Elizabeth Sheridan, RN, Egg Harbor City, NJ;

15. Barry S. Rabner, President and Chief Executive Officer, Princeton HealthCare System, Plainsboro, NJ;

16. Leslie D. Hersh, President and CEO, Saint Clare's Health System, Denville, NJ; and

17. Catherine Yaxley, Vice President, Planning and Government Affairs, Holy Name Medical Center, Teaneck, NJ.

A summary of the comments and the Department's responses thereto follows.

The numbers in parentheses following each comment below correspond to the commenters listed above.

Proximity of PCI Services to Patient Residence

1. COMMENT: A commenter states, "Patients and their families often prefer to be treated by their local physicians at facilities close to home and elective angioplasty or PCI is no different." (1)

2. COMMENT: A commenter states, "The community deserves the best medical care close to home," and residents "should not be forced to travel out of the [county] or to neighboring states to access this service." The commenter further asserts, "Hunterdon County has a growing underserved population with no public transportation options to access out-of-area facilities to receive this treatment. This has led to patients not pursuing elective angioplasty because of the inability to travel such distances, and has in turn led to repeated hospitalizations for untreated heart disease." (12)

3. COMMENT: A commenter “strongly believes the residents of Cumberland, Salem, and Gloucester counties should have immediate access to elective ... PCI services in their own communities.” The commenter states, “Each of our hospitals has the cardiac service resources and the volume of cases necessary to justify the establishment of an elective PCI program.” (13)

4.COMMENT: A commenter states that residents of “Gloucester, Salem and Cumberland Counties ... face potential health risk and economic hardship to travel outside of their respective counties, and ... out of State for ... ‘elective’ angioplasty” and that, the “regulations should be modified to allow elective angioplasties to be performed at our hospitals that currently provide emergency PCI.” (14)

RESPONSE TO COMMENTS 1 THROUGH 4: The Department acknowledges that some individuals may prefer to obtain elective PCI at local community hospitals. As part of the full review of applications for certificates of need (CN) to participate in the Atlantic C-PORT-E Study, the Department considered the issue of Statewide access to PCI without on-site surgical backup. The Department is unaware of existing access problems with elective PCI related to the ability of each community hospital to perform such services.

The commenters associate the lack of elective PCI performed at local community hospitals with increased risk to the health of the residents of this State, but none offers any substantive information to support this assertion. The Department has received neither complaints nor data supporting the commenters’ assertions. For that reason, the Department will make no change on adoption in response to the comments. The

Department will continue to consider access to health care services subject to health planning regulation in future CN calls for elective angioplasty.

Hospital Systems

5. COMMENT: A commenter supports the requirement at proposed new N.J.A.C. 8:33-3.11(c)8ii that facilities partnered under a collaboration agreement regularly consult on a case, and use technology to share case information rapidly. The commenter believes that not “all community hospitals should be performing elective PCI,” and implies that CN approval for elective angioplasty without cardiac surgery backup should be limited to hospitals that are part of a “comprehensive [cardiovascular] network,” in which “digital image transmission capabilities” support “safe, effective care” of patients throughout a region, to facilitate rapid communication between a community hospital and a [full-service] cardiac surgery program “for those rare instances when problems do occur.” The commenter states, policy “changes relative to clinical practices ... must continue to support a coordinated network approach to cardiovascular care.” (3)

RESPONSE: The Department acknowledges the commenter’s support for proposed new N.J.A.C. 8:33-3.11(c)8ii and the convenience of digital image sharing capabilities among affiliate facilities within a hospital system or network.

The collaboration agreement serves to ensure that non-network facilities can communicate with participating hospitals as promptly as may be necessary, and take advantage of technology that facilitates this communication. This requirement is in the Atlantic C-PORT-E Manual of Operations, and would continue at proposed new N.J.A.C. 8:33-3.11(c)8ii. The Department is unaware of communication issues between

participating community hospitals that are not part of a hospital network and their cardiac surgery backup partners, and the commenter does not otherwise provide a rationale for automatic exclusion of these community hospitals from participation in the State demonstration project. The Department will consider a facility's ability to comply with N.J.A.C. 8:33-3.11(c)8ii, and the relevance of membership in a network or system as it may affect that compliance, in its anticipated rulemaking.

For the foregoing reasons, the Department will make no change on adoption in response to the comment.

6. COMMENT: A commenter suggests that the Department expand the category of hospitals that are eligible to participate in the State demonstration project beyond those that are registry participants. The commenter requests that the Department permit hospitals that are part of a health care network and that do not have onsite cardiac surgical backup (mentee hospitals) to participate in the State demonstration project if the health care network to which the mentee hospital belongs includes another hospital that has cardiac surgery (mentor hospitals). The commenter states that permitting mentee hospitals "to participate in the State demonstration project [would] strengthen the database by providing additional valuable data" and would "add a layer of protection and quality that might not otherwise be available." The commenter states that hospitals in a health care network "share financial, operational, and clinical functions" to achieve "the joint delivery of high quality care." The commenter suggests rule text for a regulatory scheme in which the mentor hospital would "assume primary, exclusive and ultimate responsibility for the oversight of all the clinical programmatic staffing and

volume requirements” and “quality outcomes associated with the [mentee hospital’s] participation in the State demonstration project.” The commenter states that networked hospitals share an “identity of interests” that gives each a “heavy incentive to assure that elective PCI services are of the highest quality possible and that appropriate measures are taken to expedite the transfer of a patient needing cardiac surgery to” a mentor hospital.

The commenter attaches to the comment copies of its November 2013 and February 2014 comments on prior rulemaking activity of the Department with respect to this issue, containing its prior recommendations that the Department require participants in the prior demonstration projects to have “shared governance interests” with “the hospital or health care system ... that provides the requisite surgical back-up” and “strong clinical affiliation through a contractual agreement with an established hospital or healthcare network that has the designation as a Cardiac Surgery Center” and a “strong collaborative agreement delineating the Cardiac Surgery Center’s role in the general oversight of quality assurance for all cardiac programs at hospitals performing elective angioplasty without surgical backup on-site,” including “cross training of personnel, periodic review of ... data” such as “Door to Balloon times,” and joint Morbidity and Mortality ... conferences,” with the rationale that these requirements would enhance “communication between the organizations to assist in providing high quality care and establishing best practices.”

The commenter recommends that the Department change proposed N.J.A.C. 8:33-3.11(c) to expand eligibility to participate in the State demonstration project beyond those hospitals that the Department licensed to participate in the registry, to include

“mentee hospitals” as described above, provided they are within 50 miles of the mentor hospital, and can demonstrate compliance with the Manual of Operations volume requirements “by the third year of operation” and the patient selection protocols and device limitations by the end of the first year of licensure. The commenter recommends additional changes to proposed N.J.A.C. 8:33-3.11(c) to require “mentor hospitals” to assume “primary responsibility of the oversight of all clinical, programmatic, staffing and volume requirements” and “quality outcomes” for the mentee hospital, and cross training of personnel, data entry, creation of forms, periodic data review, joint morbidity and mortality conferences, and joint data reporting. The commenter also recommends that the Department establish December 31, 2015, as the termination date of the State demonstration project, “by which time the Department will have promulgated new rules at N.J.A.C. 8:33E for elective angioplasty without cardiac surgery backup, issued licenses” thereunder, and established minimum standards for the procedure and a Statewide certificate of need call.

RESPONSE: The Department declines to change proposed N.J.A.C. 8:33-3.11 as the commenter suggests. The changes the commenter suggests would be inconsistent with the Atlantic C-PORT-E Manual of Operations and would exceed the scope of the proposed rulemaking. To maintain consistency with the Manual of Operations, the Department will not implement these changes in the context of the State demonstration project.

The Department declines to establish December 31, 2015, as the termination date for the State demonstration project, and the date by which it shall have concluded its review of data, completed the anticipated future rulemaking process, conducted a

call for, and review of, applications for certificates of need, and issued licenses. The suggested date would permit the Department insufficient time to accomplish these tasks.

The Department will take the commenter's suggestions under consideration as it undertakes the anticipated future rulemaking at N.J.A.C. 8:33E for elective angioplasty without on-site cardiac surgery backup. (11)

Certificate of Need and Rulemaking

7. COMMENT: A commenter objects to proposed new N.J.A.C. 8:33(c), which would limit participation in the State demonstration project to hospitals that hold licensure to participate in the Atlantic C-PORT-E registry, because the rule would prevent “non-cardiac surgery centers that meet the minimum requirements” from participation. The commenter states, “the proposed changes ... essentially replace one demonstration with another.” The commenter states, “select hospitals should be allowed to provide elective PCI outside of the demonstration [project], if they can comply with the pertinent requirements and ensure patient safety.” (3)

8. COMMENT: A commenter “applauds” the Department's continued application of the full CN review process to the grant of new cardiac services pursuant to N.J.S.A. 26:2H-8, and “the Department's recognition of the Legislature's preemption in this area and the need to apply full review [CN] standards for all cardiac surgery-related services (which have historically included interventional cardiology and electrophysiology).” (10)

9. COMMENT: A commenter states that the rule proposal does not justify the need for the State demonstration project, and that “adequate data was gathered and rigorously

analyzed” through the multi-year Atlantic C-PORT-E study. The commenter states that the proposed rulemaking fails to articulate the parameters and funding source of the proposed State demonstration project, and fails to identify the qualifications of the study team or the hypotheses being tested. The commenter believes the proposed State demonstration project could lead to an indefinite delay in licensing non-participating hospitals’ performance of elective PCI services without cardiac surgery on-site. The commenter estimates that the rules proposed for readoption, and the proposed amendments, repeals, and new rules, would delay newly participating hospitals from initiation of elective PCI until 2020. The commenter recommends eliminating the State demonstration project and replacing it with direct integration of elective PCI into the mainstream of licensed acute care services.

The commenter suggests that the Department remove the CN process for elective PCI, focus its efforts on rulemaking that sets or refines the threshold standards for volume, cardiology resources, and affiliations with existing cardiac surgical providers, issue licenses for elective PCI licenses under an extension of the demonstration project rules while it establishes rules for elective PCI in the Hospital Licensing Standards at N.J.A.C. 8:43G, and replace the full CN review with expedited CN review for establishing PCI services.

The commenter recommends that if the Department deems continued study essential, the Department begin data collection immediately for the State demonstration project to avoid further delays in the rulemaking process, and convene an expert panel to ensure the Department adopts definitive elective PCI rules within 12 months of

adoption of the rules proposed for readoption, and the proposed amendments, repeals, and new rules. (13)

10. COMMENT: A commenter states that aspects of the rules proposed for readoption, and the proposed amendments, repeals, and new rules, put “certain New Jersey hospitals at a significant operational disadvantage with the very real potential of putting patient lives at risk ... The further delay and the unequal treatment of C-port versus non-C-port hospitals ... jeopardize the [Statewide] safety net of primary PCI/elective angioplasty. The expenses of providing emergency PCI are significant and becoming increasingly unsustainable. PCI programs throughout New Jersey are debating the future economic viability of sustaining ‘emergent-only’ cath labs. [The commenter estimates] that it costs [its facility] two to three million dollars per year ... to pay for the staffing, equipment and other costs necessary to provide emergent PCI services 24/7 ... If [the facility] were to eliminate the service, ... patients would have to travel to [other facilities] at rush hour. It could take an hour to reach [these facilities]. This could compromise the health – and risk the life – of the patient.” The commenter recommends that the Department extend the elective PCI licenses of the hospitals participating in the Atlantic C-PORT-E registry as proposed, and allow both participating and non-participating hospitals to be eligible for the State demonstration project in the same expedited CN process, as opposed to a full CN process after 12 months from the adoption of the rules proposed for readoption, and the proposed amendments, repeals, and new rules. (15)

11. COMMENT: A commenter states that for qualified hospitals excluded from participating in the Atlantic C-PORT-E registry, and thereafter from the State

demonstration project until the anticipated rulemaking and licensing, the wait to provide their communities and patients with elective PCI has become “unbearable.”

The commenter states that for hospitals performing only emergent PCI to wait “to provide a critical service” that the hospital already effectively provides on an emergency basis “is unacceptable and denies ... the population in our service area access to this vital service.” The commenter noted that elective PCI services are only available at one hospital “in the northwestern part” of the State and for many residents of that region, the nearest alternative is farther away than the hospital the commenter represents.

The commenter states, “Any hospital that is currently licensed to provide emergency PCI and meets current licensure standards should be allowed to apply for expedited CN review and approval within 6 months of adoption of the proposed regulations” and that, “approved [hospitals] would operate under the same demonstration license under which the existing C Port hospitals would operate until approval of new licensure regulations. All demonstration license providers would then submit for expedited CN approval for full licensure.” (16)

12. COMMENT: A commenter states that the proposed State demonstration project does not test anything that has not been evaluated already “in the Atlantic C-PORT-E trial.” The commenter states, “As written, the only effect seems to be additional administrative [burdens] for both the Department and participating hospitals,” and suggests that the Department should “re-think its rationale and need for this duplicative demonstration.” (17)

RESPONSE TO COMMENTS 7 THROUGH 12: The complexity of the subject matter, the strong divergence of opinions expressed at the Department's public hearings on this

matter and at the November 27, 2012, State symposium entitled, “PCI in Facilities Without Cardiac Surgery On Site - An Expert Panel Review,” and the fact that only modest changes have occurred Statewide in elective angioplasty volume over the past five years (23,255 in 2014, 22,947 in 2013, 22,365 in 2012, 22,678 in 2011 and 23,633 in 2010) are reasons that compel the Department to move carefully and thoughtfully before adopting future cardiac rules at N.J.A.C. 8:33E.

The Department expects the State demonstration project to last no more than 18 months. The Department would consider the outcome of the State demonstration project and the Atlantic C-PORT-E Study and registry in the anticipated rulemaking. The Atlantic C-PORT-E Study expressly limited its findings to apply only within the parameters therewith, and not necessarily to extend to the general population or to any hospital with a cardiac catheterization laboratory.

The rules proposed for readoption, and the proposed amendments, repeals, and new rules, would allow the Department additional time to explore fully the subject matter as it pertains to the promulgation of elective PCI rules at N.J.A.C. 8:33E. The Department believes the additional information provided by the State demonstration project and the allotted study length at N.J.A.C. 8:33-3.11(c) are reasonable and necessary to inform its anticipated rulemaking.

The Department wants the State demonstration project to track as closely as possible the conditions existing during the Atlantic C-PORT-E Study and registry. Therefore, the Department declines to amend existing N.J.A.C. 8:33-3.11(c) to expand eligibility to participate in the demonstration project beyond hospitals currently participating in the registry, as the commenters suggest.

The Department declines to “eliminate the State demonstration project” and “directly [integrate] elective PCI into the mainstream of licensed acute care services” because of the likely negative effect it would have on Statewide volume criteria for interventionalists and hospitals. The Department declines to eliminate CN requirements and expedited review of CN applications for participation in the State demonstration project. The Department acknowledges a commenter’s support of the Legislative mandate for CN review of proposed cardiac services to preserve the viability of certain health care services. Pursuant to N.J.S.A. 26:2H-7.a and 7.c, PCI is not exempt from the CN process.

This is consistent with the Department’s statutory obligations. N.J.S.A. 26:2H-6.1.h states that the CN process is necessary to maintain the quality of certain health care services by “limiting the proliferation of [those services] to protect the viability of the services as well as the providers now rendering them.” The CN process is a mechanism to ensure access to high quality interventional cardiac services.

The Department acknowledges the cost to maintain emergent-only PCI services and anticipates that the proposed State demonstration project would inform the Department’s decision whether to permit elective PCI at facilities without cardiac surgery backup as a regular hospital service in the anticipated rulemaking.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

COMMENT 13: A commenter supports the Department’s effort to foster quality and access through the development of specific requirements to allow more hospitals to

provide elective PCI. The commenter states that although research has concluded that elective PCI without cardiac surgery backup is safe, not all cardiac catheterization programs have the qualifications to provide these services. The commenter recommends that the Department, in consultation with the Cardiovascular Health Advisory Panel, promulgate rulemaking that would incorporate patient safety quality measures, including the following requirements: catheterization laboratory accreditation through the American Heart Association (AHA) and the Society for Cardiovascular Angiography and Interventions (SCAI); linkage of peer review to a cardiac surgery center and/or external sources to adjudicate cases; and establishment of criteria to evaluate the appropriateness of proposed new providers. (2)

14. COMMENT: A commenter supports the continuation of both the CN process and licensing for cardiac services and believes that the CN program is “an important regulatory tool through which our [State] can address changing healthcare needs, the orderly evolution of services and control the unnecessary proliferation of costly services that require highly trained technical staff.” (3)

15. COMMENT: Commenters support and appreciate the State demonstration project and the expedited CN process as an interim measure that will allow hospitals participating in the Atlantic C-Port-E registry (that is, “eligible hospitals” pursuant to proposed new N.J.A.C. 8:33-3.11(c)), to continue to participate in the State demonstration project until the Department can conclude the anticipated rulemaking and the issuance of licenses under the anticipated rules. (2 and 4-9)

RESPONSE TO COMMENTS 13 THROUGH 15: The Department acknowledges the commenters’ support of the proposed rulemaking.

16. COMMENT: A commenter inquires whether the Department intends to allow the licenses of eligible hospitals to remain effective during the anticipated rulemaking and licensure, and whether the Department would require hospitals to which the Department does not issue CNs to cease performing elective PCI and to relinquish their licenses on the date the Department issues CNs to other facilities. (10)

RESPONSE: Licenses issued to eligible hospitals to participate in the State demonstration project would remain effective during the anticipated rulemaking and the issuance of licenses under the anticipated rules. The Department would require a hospital participating in the State demonstration project to which the Department does not issue a CN and license following the anticipated rulemaking to cease performing elective PCI and to relinquish its license within 30 days of the Department's decision not to issue a CN and license to that hospital.

17. COMMENT: Commenters recommend that the Department authorize eligible hospitals to obtain licensure under expedited rather than full CN review in the anticipated rulemaking and licensing. The commenters state that this would permit eligible hospitals to continue to provide elective PCI services during the anticipated rulemaking and licensing, and note that eligible hospitals have already undergone two full CN review processes, including public hearings before the New Jersey State Health Planning Board. The commenters state that the Department has twice determined, under the tenure of two different Commissioners, that the eligible hospitals met the Department's health planning objectives and could perform elective PCI safely and

effectively, and that the eligible hospitals' participation did not adversely affect cardiac services in neighboring cardiac surgery centers. (2, 4-9, and 17)

18. COMMENT: Commenters state that the eligible hospitals have invested considerable time and resources to participate, and that their participation has contributed data on both a Statewide and multi-state level, and has led to changes in the national clinical guidelines allowing elective PCI without surgery on-site. They state that requiring the eligible hospitals to undergo a competitive full CN review process pursuant to N.J.A.C. 8:33-3.11(c)16ii, during which they would risk losing their ability to provide the elective PCI services in which they have heavily invested and have been safely providing for over 10 years, is illogical and bad policy. The commenters state that, for these reasons, the Department should treat eligible hospitals differently from ineligible hospitals and grant them licensure under the anticipated rulemaking, subject only to their meeting the requirements of that anticipated rulemaking. (4, 6, 7, 8, and 9)

RESPONSE TO COMMENTS 17 AND 18: The Department disagrees with the assertion that it should grant preferential treatment to eligible hospitals based on their expenditure of resources. The issues that arise with respect to the provision of elective angioplasty throughout the State are complex, and the Department is obliged to consider the impact that an expansion of elective angioplasty would have on existing cardiac surgery centers. The demonstration project seeks geographic distribution across the State for a limited duration, which would minimize the impact on existing providers.

For the foregoing reasons, the Department will make no change upon adoption in response to the comments.

19. COMMENT: Several commenters request that the Department change proposed new N.J.A.C. 8:33-3.11(c)16 to indicate that the State demonstration project is not limited to 18 months, and that the Department would issue CNs and licenses to hospitals participating therein under the anticipated rulemaking without full CN review. The commenters state that the proposal Summary, and the Department's presentation of the proposed rulemaking before the HCAB, indicate that the State demonstration project CNs and licenses would remain in effect until the Department concludes the anticipated rulemaking and licensure. (2, 6, 7, and 9)

RESPONSE: The Department agrees in part and disagrees in part. Proposed new N.J.A.C. 8:33-3.11(c)16 does not reflect the text as the Department submitted it for publication, does not reflect the Department's stated intention, and is grammatically incorrect. The Department states in the notice of proposal Summary, "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." See 47 N.J.R. 319(a), 321.

To correct this, the Department will change proposed new N.J.A.C. 8:33-3.11(c)16 (to be recodified as paragraph (c)17) on adoption to note that while the Department intends the State demonstration project to last no more than 18 months,

licenses to participate therein are to remain in effect until the Department concludes the anticipated rulemaking and licensure.

The Department disagrees with the suggestion that it should authorize participating hospitals to obtain licensure under the anticipated rulemaking without full CN review for the reasons stated in response to previous comments.

20. COMMENT: Several commenters would support requiring hospitals that are not eligible hospitals to be subject to full CN review for licensure under the anticipated rulemaking. (2, 4, 5, 7, 9, and 17)

RESPONSE: The Department acknowledges commenters' support and notes that all applicants for CN and licensure would be subject to full CN review for licensure under the anticipated rulemaking, for the reasons stated in response to previous comments.

21. COMMENT: A commenter notes that the notice of proposal does not mention elderly persons, refers to N.J.A.C. 8:33-4.10, and objects, stating that elderly persons are an important population and have high need for health services, especially for cardiac services. The commenter wants to ensure this group remains part of the specific criteria for CN review. (2)

RESPONSE: The rules proposed for readoption, and the proposed amendments, repeals, and new rules, would readopt existing N.J.A.C. 8:33-4.10 without change. The exclusion from the published notice of proposal of unchanged rule text proposed for readoption is consistent with New Jersey Office of Administrative Law style conventions

for the New Jersey Register. Therefore, the Department will make no change on adoption in response to the comment, as none is necessary.

22. COMMENT: A commenter “endorses” the proposed readoption of N.J.A.C. 8:33, particularly N.J.A.C. 8:33-4.10, which establishes specific CN review criteria, including “the promotion of access to care by low income, racial and ethnic minorities, women, disabled persons and person with HIV infections.” The commenter states that lack of growth in elective PCI despite the approval of 11 new hospitals over six years shows that additional approvals did not expand access in this area, and that Atlantic C-PORT-E providers simply gained ground while existing providers lost patients. The commenter states that this is a “concerning pathway,” and that protecting access to vulnerable individuals should remain a State priority. (10)

RESPONSE: The Department acknowledges the commenter’s support of the rules proposed for readoption and the proposed amendments, repeals and new rules, and agrees with the assertion that protecting access to vulnerable individuals should remain a State priority.

Results of Atlantic C-PORT-E Study

23. COMMENT: A commenter states that complication rates for PCI were high when PCI was available only in settings where cardiac surgery was performed, that over time, technology and physician experience have made the procedure safer, and that, “Emergency cardiac surgery rates resulting from PCI procedures are well under one percent and overall complication rates are also low. However, it is still important that

centers providing PCI without on-site surgical backup have mechanisms in place to ensure high-quality care.” (1)

24. COMMENT: A commenter states, “Medical science has evolved to the point that elective PCI can be safely performed without on-site cardiac surgery, provided quality conditions are maintained ... Programs that can comply with these requirements should be allowed to perform elective PCI.” (3)

25. COMMENT: A commenter states that the “lack of elective angioplasty” at its hospitals presents a “barrier to safe and immediate access to care for patients having a cardiac event,” as it forces the transfer and physical transport of patients requiring elective PCI to facilities outside of the immediate region. (12)

26. COMMENT: A commenter states, “The lack of ... capability [of hospitals currently performing emergency PCI to perform elective PCI without on-site surgical backup] creates an unnecessary risk to cardiac patients from a public health perspective and makes the emergency PCI programs at each hospital much less cost-effective to operate.” (13)

27. COMMENT: A commenter states, “Scientific evidence, as established by a nationally-recognized study published in The New England Journal of Medicine, has demonstrated that there is no difference in elective angioplasty outcomes whether cardiac surgery was on site or not.” (14)

RESPONSE TO COMMENTS 23 THROUGH 27: The Department agrees that elective PCI without on-site surgical backup requires mechanisms in place to ensure high-quality care. The Department acknowledges that the Atlantic C-PORT-E Study concluded that PCI performed without on-site surgical backup is as “safe” as being conducted at a

hospital with a full service cardiac surgery program, but qualified this conclusion by stating that those outcomes exist only within the parameters of that Study, and that those findings do not necessarily extend to the general population or to every hospital with a cardiac catheterization laboratory. “Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery”, Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S and Li Liu, M.D. for the Atlantic CPORT Investigators, New England Journal of Medicine, 366:19, May 10, 2012. The State demonstration project would further explore these conclusions.

The Department disagrees with the assertion that limiting participation in the State demonstration project to eligible hospitals presents a “barrier to safe and immediate access to care for patients having a cardiac event,” or “ creates an unnecessary risk to cardiac patients from a public health perspective ...” The commenters do not offer any substantive information to support this assertion. The Department has received neither complaints nor data supporting the commenters’ assertions in this regard.

As stated in response to previous comments, the Department acknowledges the cost to maintain emergent-only PCI services and anticipates that the proposed State demonstration project would inform the Department’s decision whether to permit elective PCI at facilities without cardiac surgery backup as a regular hospital service in the anticipated rulemaking.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

Adherence to AHA Guidance and the 2014 Consensus Document

28. COMMENT: A commenter states that on March 7, 2012, the AHA, in conjunction with the American College of Cardiology Foundation (ACC) and the SCAI issued updated recommendations for PCI without on-site surgical backup (AHA Guidance), and that the AHA Guidance “was built on what was learned from the Atlantic C-PORT-E trial that was presented at AHA’s Scientific Sessions in 2011.” The commenter describes the AHA Guidance as recommending that each jurisdiction “should require PCI programs without surgical back up to participate in programs like [the ACTION Registry[®] – GWTG[™] (GWTG is an acronym for “Get with the Guidelines”), the] National Cardiovascular Data Registry (NCDR) or the Atlantic Cardiovascular Patient Outcomes Research Team ..., to monitor their quality and outcomes, allowing program leaders to show their commitment to quality by subjecting their program performance to independent peer review. Although the proposed regulations require facilities in the State demonstration project to collect all the information that the [NCDR] requires, [they do] not require facilities to participate in the program, only to report that information to the Data Monitor. To get the full benefits, facilities should be required to fully participate in [the ACTION Registry[®] – GWTG[™]] or one of the other programs mentioned above.” The commenter describes the AHA Guidance as recommending that hospitals licensed to perform PCI without cardiac surgery backup should “include only AHA/ACC-qualified operators who meet standards for training and competency. (1)

RESPONSE: Proposed new N.J.A.C. 8:33-3.11(c)4xiv would require participants in the State demonstration project to collect and submit data to the Data Monitor. This

requirement is comparable, if not identical, to the data collection and submission standards of the Atlantic C-PORT-E Study and registry and the NCDR. This requirement would maintain the integrity of the State demonstration project and allow comparisons to the Atlantic C-PORT-E Study and registry results. Participating hospitals might elect to contribute, independently of the State demonstration project, data to the NCDR and the ACTION Registry[®] – GWTG[™]. For these reasons, the Department will make no change on adoption in response to the comment.

29. COMMENT: A commenter describes the AHA Guidance as recommending that hospitals licensed to perform PCI without cardiac surgery backup “adhere to strict patient-selection criteria (e.g., exclusion of patients with [ejection fraction of less than 30], and “have an annual institutional volume of at least 200 to 400 cases.” (1)

30. COMMENT: A commenter states that, even with the CN process in place to monitor the proliferation of certain health care services, New Jersey currently has excess cardiac capacity, as almost half of the surgery centers do not currently meet the required minimum 350 cardiac surgery procedures. (3)

31. COMMENT: A commenter states that the Department, in developing the anticipated rulemaking, should treat as an important consideration that Statewide “elective PCI volumes have not varied more than 0.02 [percent] from the highest year to the lowest between 2007 (the year in which the earliest Atlantic C-PORT-E licenses were awarded) and 2013 (the latest full year of reporting); and the difference in volume between 2007 and 2013 is a 54 case decrease, showing that the licensure of the additional Atlantic C-PORT-E hospitals simply caused a shifting of cases from existing

providers.” The commenter states that the Department should consider, in examining a future CN call, the impact on hospital volume, including the minimum volume per teaching fellow at teaching hospitals. (10)

32. COMMENT: A commenter states that proposed new N.J.A.C. 8:33-3.11(c)4ii would not address guideline changes set forth in the “SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup.” Dehmer, Gregory J., James C. Blankenship, Mehmet Cilingiroglu, James G. Dwyer, Dmitriy N. Feldman, Timothy J. Gardner, Cindy L. Grines, and Mandeep Singh. *Circulation*. 2014;129:2610 (published online before print March 17, 2014) (2014 Consensus Document). (17)

RESPONSE TO COMMENTS 29 THROUGH 32: The Department acknowledges that proposed new N.J.A.C. 8:33-3.11(c)4ii would establish volume requirements that are not consistent with those the AHA Guidance and the 2014 Consensus Document recommend. Proposed new N.J.A.C. 8:33-3.11(c) would permit the State demonstration project to replicate the institutional volume requirements of the Atlantic C-PORT-E Study and registry, which is 200 PCIs per institution, and enable comparison of the results of the State demonstration project to the Atlantic C-PORT-E Study and registry results. For that reason, the Department will make no change to the proposed rules, but will consider whether volume requirements set forth in N.J.A.C. 8:33E should be changed in its development and consideration of the anticipated rulemaking.

Hospitals that would be eligible to participate in the State demonstration project are licensed general hospitals subject to N.J.A.C. 8:33E-2.4(e) and 8:43G-7.29(a), which establish standards consistent with those the commenter describes.

Proposed new N.J.A.C. 8:33-3.11(c) would require adherence to the inclusion criteria, including volume requirements, through licensure evaluation and examination by the Data Monitor to ensure participating hospitals' compliance. Proposed new N.J.A.C. 8:33-3.11(c)4ii would exceed the 2014 Consensus Document's suggested volume requirement that operators should perform 50 PCIs per year. As explained above, the rules proposed for readoption, and the proposed amendments, repeals, and new rules reflect a determination to replicate the Atlantic C-PORT-E Study's and registry's institutional and physician volume requirements of 200 PCIs per institution and 75 PCIs per physician annually. The Department will take into consideration the AHA Guidance and the guideline changes set forth in the 2014 Consensus Document in its anticipated rulemaking.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

33. COMMENT: A commenter describes the AHA Guidance as recommending that hospitals licensed to perform PCI without cardiac surgery backup should "demonstrate appropriate planning for program development and should complete both a primary and elective PCI development program to include routine care process and case selection review ... develop and maintain a quality and error management program," and "perform PCI 24 hours a day/7 days a week." (1)

RESPONSE: The Atlantic C-PORT-E Study and registry protocols required participating facilities to plan and complete a primary and elective PCI development program of routine case processing and case selection review, to maintain a quality and error

management program, and to make primary PCI available around the clock. These requirements are consistent with the AHA Guidance. Adherence to the protocols was a condition of licensing that would continue under proposed new N.J.A.C. 8:33-3.11(c). Therefore, the Department will make no change on adoption in response to the comment.

34. COMMENT: A commenter describes the AHA Guidance as recommending that participating hospitals develop “and sustain agreements with an ambulance service capable of advanced life support and [intra-aortic balloon pump (IABP)] transfer that guarantees a 30-minute-or-less response time,” and notes that proposed new N.J.A.C. 8:33-3.11(c) would not require an agreement with an ambulance service, although it would require sending facilities to transfer patients to cardiac surgery centers, and that cardiac surgery centers receive transferred patients, within one hour of the determination to transfer, including patients who require transport for an IABP. (1)

RESPONSE: Proposed new N.J.A.C. 8:33-3.11(c)8i would not require ambulance service agreements. Existing N.J.A.C. 8:33E-2.16 likewise does not require ambulance service agreements. Under either rule, hospitals must be able to move a patient in need of emergency cardiac surgery within an hour to a cardiac surgery center operating room. A participating hospital may interpret proposed new N.J.A.C. 8:33-3.11(c)8i to include an ambulance service agreement.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Teaching Hospitals

35. COMMENT: A commenter states that the Department should give “special consideration ... to the State’s teaching programs when reviewing the expansion of programs under the CN review process,” and states that the expansion of elective PCI, specifically to teaching hospitals, is critically important and must be given priority to maintain the integrity and viability of medical education programs throughout New Jersey. The commenter states that the Accreditation Council for Graduate Medical Education (ACGME) requires sponsoring institutions of internal medicine training programs to provide a broad range of facilities and clinical support services and comprehensive care to adult patients, including cardiac catheterization. The commenter states that “teaching hospitals that are without comprehensive cardiac catheterizations services may be at risk of losing their accreditation. This has the potential to reduce the pipeline for primary care physicians and may have significant ramifications on the physician workforce in New Jersey for decades to come.” (2)

RESPONSE: The ACGME accreditation of graduate medical education in internal medicine requires only that a cardiac catheterization laboratory be available at the sponsoring institution. Accreditation programs in internal medicine and cardiovascular disease require the availability of cardiovascular interventional procedures. These upper level teaching programs are only found at six of the 18 New Jersey cardiac surgery centers. Therefore, the rules proposed for readoption, and the proposed amendments, repeals, and new rules, would not have a direct impact on New Jersey’s

teaching programs at non-cardiac surgery centers. Therefore, the Department will make no change on adoption in response to the comment.

36. COMMENT: A commenter inquires whether the Department is changing the Atlantic C-PORT-E Manual, whether the Department would communicate these changes, if any, to applicants for licensure to participate in the State demonstration project prior to the deadline for submission of applications, and whether the Department has identified a Data Monitor and the key questions the Data Monitor and the State would address in State demonstration project. (2)

RESPONSE: The rules proposed for readoption, and the proposed amendments, repeals, and new rules, would establish a State demonstration project that replicates the reporting requirements of the existing Atlantic C-PORT-E registry. Once the State demonstration project becomes operational, the Atlantic C-PORT-E Manual would be inapplicable.

The Data Monitor would be a person who is qualified to perform the functions specified in the definition of “Data Monitor” at proposed new N.J.A.C. 8:33-1.3. The Department intends to engage Thomas R. Aversano, M.D., Director, Atlantic C-PORT Projects, Associate Professor of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, to serve in this capacity.

The purpose or “key questions” of the proposed State demonstration project are to inform the Department’s development of clinically sound Statewide policy on elective angioplasty; to continue the collection and analysis of scientifically rigorous data that would contribute significantly to New Jersey’s evidence base on the safety and efficacy

of elective PCI without on-site cardiac surgery backup; and to compare the results of the State demonstration project with the results of the Atlantic C-PORT-E Study and registry.

37. COMMENT: A commenter inquires as to the differences, if any, in data monitoring and/or reporting during the State demonstration project as compared to the Atlantic C-PORT-E Study and registry. (10)

RESPONSE: The Atlantic C-PORT-E Study established an Events Committee and a Data Safety Monitoring Board. The Events Committee's charge was to review and adjudicate all potentially major adverse outcomes and to report its findings to the Data Safety Monitoring Board. The Data Safety Monitoring Board's charge was to recommend actions it deemed appropriate in response to the adverse event.

In contrast, the proposed State demonstration project would use the expertise of the Data Monitor to review and adjudicate all potential adverse events and to recommend appropriate responsive actions to the Department. The Department would make final agency decisions in response to adverse events. The Department would continue to maintain its ongoing surveillance of all licensed cardiac services providers for compliance with existing licensing requirements for cardiac services at N.J.A.C. 8:33E and 8:43G-7. The Department responds to complaints regarding licensed cardiac services providers as it does with respect to other licensed health care facilities. N.J.A.C. 8:33E-1.13 and 2.13 establish procedures to which the Department adheres in addressing non-compliant cardiac services, including, among other measures, requiring review by an independent external organization approved by the Department to assess

overall performance of a facility and its staff, and requiring detailed plans of correction to ensure that non-compliant facilities implement time-sensitive corrective actions to achieve compliance.

38. COMMENT: A commenter requests that the Department and/or the Data Monitor periodically report “volumes and other data” during the course of the State demonstration project and post the reports on the Department’s website. The commenter requests that, to permit for complete transparency in the process and outcome, the Department not invoke the law governing access to government records.
(10)

RESPONSE: The Department periodically generates, publishes, and posts to its website, reports with respect to cardiac services that include cardiac surgery center performance reports, commonly referred to as “report cards,” which are risk-adjusted and contain quality and outcome measures, reports that track historical performance of low-risk and full-service cardiac catheterization facilities, and annual and quarterly cardiac services facility utilization reports. If the Department, in the ordinary course of business, finalizes reports using the data it collects pursuant to proposed new N.J.A.C. 8:33-3.11(e)6vii, the Department would make publicly available those reports, and may post them to its website. The Department is without authority to disregard applicable law, including laws governing access to government records. Without prejudging any request under laws governing access to government records, applicable exclusions from disclosure pursuant to that law, and the integrity of the State demonstration project, are likely to prohibit the dissemination of interim reports while the State

demonstration project is ongoing. The final report of the State demonstration project would be available upon finalization and acceptance by the Commissioner.

39. COMMENT: A commenter inquires whether hospitals participating in the State demonstration project that fail to adhere to proposed new N.J.A.C. 8:33-3.11(c)2 over the course of the State demonstration project would be subject to licensure consequences. (10)

RESPONSE: Hospitals that the Department licenses to participate in the State demonstration project would be subject to proposed new N.J.A.C. 8:33-3.11(c)2 over the course of the State demonstration project. Participating hospitals also would be subject to N.J.A.C. 8:33E, 8:43E, and 8:43G-7, which establish cardiac facility licensure requirements, procedures for licensure enforcement actions, and sanctions, such as civil monetary penalties and disciplinary action, up to and including facility license revocation. The proposed amendment at N.J.A.C. 8:33-3.11(c)13 would cross-refer to N.J.A.C. 8:33E-2.3(d), which establishes standards for licensure enforcement of PCI services.

40. COMMENT: Commenters recommend that the Department change proposed new N.J.A.C. 8:33-3.11(c)4xvi to extend the time for the collection and submission of data in the regular course from “within 24 hours” to require participating facilities “to initiate” collection and submission within 24 hours and to complete submission as N.J.A.C. 8:33E-1.9 and 2.10 require. They state that requiring reporting of adverse events within one hour of occurrence “could interfere with the clinical activities of the catheterization

lab, where the nature of the event requires follow-up procedures for the patient,” and is unreasonable and impractical because the employee responsible for data collection might not be on duty at the time of the adverse event.

They request that the Department change proposed new N.J.A.C. 8:33-3.11(c)4xvii to extend the time for the collection and submission of data upon the occurrence of adverse events from “within one hour” to “within 72 hours.” The commenters state that the change would recognize that collection and submission of all relevant data for routine reporting could take days or weeks. Several commenters note that “the C-PORT-E Adverse Event Reporting Requirements specify that a report must be submitted within 72 hours of occurrence for ‘death from any cause’ or ‘emergency CABG due to a PCI complication.’ Reports of other adverse events, such as ‘recurrent myocardial infarction, stroke, bleeding, vascular surgery/repair, unplanned cardiac catheterization, any subsequent PCI, CABG for any reason or renal failure,’ must be reported within seven days.” They state that changes to proposed new N.J.A.C. 8:33-3.11(c)4xvi and xvii are necessary to make the reporting requirements for the State demonstration project consistent with the reporting obligations of the Atlantic C-PORT-E Manual of Operations. (2, 6, 8, and 9)

RESPONSE: The Department agrees with the commenters. As stated in response to prior comments, the Department clearly intended that the State demonstration project track the requirements of the Atlantic C-PORT-E Manual of Operations. Proposed new N.J.A.C. 8:33-3.11(c)4xvi and xvii are not consistent with the Manual of Operations and would impose an undue burden on participating hospitals, without appreciably enhancing patient safety or data quality. Therefore, the Department will make a change

on adoption to N.J.A.C. 8:33-3.11(c)4xvi and xvii to extend the respective data collection and reporting obligations therein to be consistent with the Atlantic C-PORT-E Manual of Operations.

Informed Consent

41. COMMENT: Commenters request that the Department change the requirements for obtaining patients' informed consent at proposed new N.J.A.C. 8:33-3.11(c)5 and the exclusionary criteria for participation in the State demonstration project at N.J.A.C. 8:33-3.11(c)9 to authorize participating facilities to adhere to each facility's particular policies and procedures for obtaining informed consent and to authorize substituted consent for incapacitated persons (that is, the consent of a relative, guardian, or other legal representative of an incapacitated patient) to undergo elective PCI without cardiac surgery backup and to participate in the State demonstration project. They assert that proposed new N.J.A.C. 8:33-3.11(c)5 and 9 would prevent a patient with any degree of dementia from obtaining elective PCI at hospitals participating in the State demonstration project. (2 and 4)

RESPONSE: The Atlantic C-PORT-E Manual of Operations excludes patients who are incapable of providing their own informed consent from enrollment eligibility. Proposed new N.J.A.C. 8:33-3.11(c)5 and 9 would maintain this exclusion to maintain consistency with Atlantic C-PORT-E Manual of Operations. This will facilitate and validate comparisons between the results of the State demonstration project and the Atlantic C-PORT-E Study and registry. Based on the foregoing, the Department will make no change on adoption in response to the comment.

42. COMMENT: A commenter recommends that the Department change proposed new N.J.A.C.8:33-3.11(c)5 and 9 to authorize enrollment into the State demonstration project of patients who are elective PCI candidates and who would otherwise be eligible for enrollment but for the fact that they had earlier diagnostic catheterizations at either participating facilities (on an emergent, that is “primary,” basis) or non-participating facilities. The commenter states that patients who obtain diagnostic catheterizations at non-participating facilities may be referred to interventionalists practicing at participating facilities. The commenter states that the recommended change would be consistent with the Atlantic C-PORT-E Study and registry protocols, maintain physician referral patterns and volumes, and preserve continuity of care. (6)

RESPONSE: The Department agrees with the commenter’s suggestion. For the reasons the commenter states, the Department will make a change on adoption at N.J.A.C. 8:33-3.11(c)5 and add new paragraph (c)6. These changes would delete the preclusion from enrollment into the State demonstration project of patients who have already received diagnostic cardiac catheterization at non-participating hospitals or emergent PCI at participating hospitals, permit referrals of patients receiving diagnostic catheterizations at non-participating hospitals to interventionalists who practice at participating hospitals, and maintain consistency with the Atlantic C-PORT-E Study and registry protocols to facilitate result comparisons.

43. COMMENT: Commenters recommend deletion of N.J.A.C. 8:33-3.11(c)5ii because it “seems to indicate that surgery in the State demonstration project creates a safety

risk. Based on the C-PORT-E Study results and the change in clinical Guidelines, it has been determined that there is no significant safety risk related to having an elective PCI procedure at a hospital without surgery on-site. Moreover, as drafted, the informed consent required is misleading because it suggests that cardiac surgery centers have operating rooms and surgeons on call and available during elective PCI procedures, when that is simply not the case. In practice, there may be delays in transferring a patient to an operating room in a cardiac surgery center because a surgeon is unavailable or an operating room is in use. There could be as much of a delay in transferring a patient to an operating room in a cardiac surgery center as there is in transferring the patient from a hospital without surgery on-site to a cardiac surgery center.” (8 and 9)

RESPONSE: The Department disagrees with the commenters’ representation of the results of the Atlantic C-PORT-E Study as generally applicable to all populations. As stated in response to previous comments, the Atlantic C-PORT-E Study report expressly limited its findings as applying only within the parameters therewith, and not necessarily applying to the general population or to any hospital with a cardiac catheterization laboratory. Proposed new N.J.A.C. 8:33-3.11(c)5ii (recodified upon adoption as N.J.A.C. 8:33-3.11(c)6ii) accurately reflects existing standards applicable to the performance of elective PCI in New Jersey, outside of the proposed State demonstration project, and does not characterize elective PCI at facilities participating in the State demonstration project as necessarily creating a safety risk. Based on the foregoing, the Department will make no change on adoption in response to the comment.

44. COMMENT: A commenter states that proposed new N.J.A.C. 8:33-3.11(c)5iii “notes that an enrolled patient may not be eligible for elective PCI at a participating hospital if the enrolled patient needs cardiac surgery” and recommends that “PCI should be allowed if necessary to stabilize a patient for transport to the cardiac surgery center for surgery.” (2)

RESPONSE: The Department disagrees with the commenter’s characterization of proposed new N.J.A.C. 8:33-3.11(c)5iii (recodified upon adoption as N.J.A.C. 8:33-3.11(c)6iii). Proposed new N.J.A.C. 8:33-3.11(c)5iii (recodified upon adoption as N.J.A.C. 8:33-3.11(c)6iii) accurately states the required information that participating hospitals are to give patients about their ability and plans for emergency transport if it were to become necessary, in obtaining patients’ informed consent to enrollment in the State demonstration project. It does not comment on specific interventions that may be appropriate to stabilize patients in the event transfer is necessary. Therefore, the Department will make no change on adoption in response to the comment.

45. COMMENT: Commenters recommend that the Department delete proposed new N.J.A.C. 8:33-3.11(c)5iv and v because they reflect patient criteria for elective PCI and, therefore, are not appropriate elements of a consent form to be signed by those who have met the criteria. A commenter suggests alternative language at N.J.A.C. 8:33-3.11(c)5v that states, “For ineligibility based on the reasons cited in N.J.A.C. 8:33-3.11(c)5iv above, or due to a patient’s informed decision not to proceed with the procedure at the study site, a participating hospital would transfer an enrolled patient to

a licensed cardiac surgery center of the patient's choosing for appropriate care.” (6, 8, 9, and 10)

RESPONSE: Proposed new N.J.A.C. 8:33-3.11(c)5iv and v (recodified upon adoption as N.J.A.C. 8:33-3.11(c)6iv and v) articulate standards for patient informed consent to enrollment in the State demonstration project, not to the receipt of elective PCI. It is appropriate to require patients to understand the elements of the State demonstration project. These standards would require participating hospitals to provide information to patients that is accurate and consistent with requirements for obtaining patient's informed consent to enroll in the Atlantic C-PORT-E Study and registry. Therefore, the Department will make no change on adoption in response to the comments.

Collaboration Agreements

46. COMMENT: A commenter inquires whether hospitals participating in the State demonstration project are to assign patients “randomly ... to their existing Atlantic C-PORT-E Study Partner Hospital as was originally done during the Atlantic C-PORT-E demonstration project? If so, how will this be monitored? If not, what is the purpose of the collaboration agreement [that proposed new N.J.A.C. 8:33-3.11(c)7 (recodified upon adoption as N.J.A.C. 8:33-3.11(c)8) would require] and is it different from a transfer agreement? Where will patients in need of rescue be sent?” (10)

47. COMMENT: A commenter describes the AHA Guidance as recommending that participating hospitals develop and maintain necessary agreements with tertiary facilities that agree to accept emergent and non-emergent transfers for additional medical care, cardiac surgery, or IABP. The commenter acknowledges that proposed

new N.J.A.C. 8:33-3.11(c)8 (recodified upon adoption as N.J.A.C. 8:33-3.11(c)9) would require a written collaboration agreement with a cardiac surgery center, but would not require a tertiary facility to accept emergent and non-emergent transfers for additional medical care or IABP. (1)

RESPONSE TO COMMENTS 46 AND 47: Although randomization was part of the Atlantic C-PORT-E Study, it was not a component of the Atlantic C-PORT-E Registry. Because the proposed State demonstration project would replicate the standards of the Atlantic C-PORT-E registry, randomization should not be a component of the State demonstration project, and the Department will make no change on adoption in response to the comment. The Department would monitor participant compliance through the Data Monitor.

Proposed new N.J.A.C. 8:33-3.11(c)8 (recodified upon adoption as N.J.A.C. 8:33-3.11(c)9) would require participating hospitals to have a collaboration agreement with a cardiac surgery center in the same or a contiguous county to transfer enrolled patients who require cardiac surgery, including patients having IABPs, to a cardiac surgery operating room within one hour of the determination of need for the transfer. This would be consistent with existing N.J.A.C. 8:33E-2.16(b) governing emergency PCI. Existing N.J.A.C. 8:33E-1.8 requires facilities that provide invasive cardiac diagnostic services without cardiac surgery backup onsite to develop and maintain written agreements with at least one cardiac surgery center to provide emergency backup and transport. Existing N.J.A.C. 8:33E-2.7 requires cardiac surgery centers to enter into written transfer agreements to accept cardiac patients from hospitals located within the same or contiguous counties.

Hospitals may have emergency transport agreements with more than one cardiac surgery center. The decision of where to transport a patient is based on multiple factors. The collaboration agreement with a cardiac surgery center would serve as an added safeguard to ensure access to on-call cardiac surgery backup.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Deletion of Standards Authorizing Inner City Cardiac Satellite and Bloodless Surgery Demonstration Projects

48. COMMENT: A commenter supports the proposed deletion of standards governing inner city cardiac satellite and bloodless surgery demonstration projects because “these demonstration projects are outdated and are no longer relevant.” (3)

RESPONSE: The Department acknowledges the commenter’s support for the proposed deletion of inner city cardiac satellite and bloodless surgery demonstration projects.

49. COMMENT: A commenter states that the inner city cardiac satellite demonstration project “demonstrated its original benefit” and expresses concern about the potential disruption created by the proposed deletion of the demonstration project rules at existing N.J.A.C. 8:33-3.11(c) and (d). The commenter requests that the Department to continue licensure of this “needed service.” (2)

RESPONSE: There remains only one facility that is operating an inner city cardiac satellite demonstration project, and the Department is working with that facility to prevent disruption to that service by an alternative form of licensure. Because there will

be no disruption in the service provided by that facility, the Department will make no change on adoption in response to the comment.

Summary of Agency-Initiated Change:

The Department is making technical changes on adoption at proposed new N.J.A.C. 8:33-3.11(c) and (c)1 to delete two placeholders for dates that were determinable by the effective date of the proposed amendments and to add instead the actual dates, calculated based on the publication date of the notice of adoption. The Department is also proposing technical changes therein to simplify sentence structure.

Federal Standards Statement

The Department is adopting neither the readopted rules nor the adopted amendments, repeals, and new rules under the authority of, or to implement, comply with, or participate in, any Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

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

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

8:33-3.11 Demonstration and research projects

(a) – (b) (No change.)

(c) The Commissioner shall accept certificate of need applications for the State demonstration project from eligible hospitals, which are those facilities *[licensed by

the] **holding** Department [on (the effective date of this amendment)] **licensure** to participate in the Atlantic C-PORT-E registry **as of August 17, 2015**.

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] **in accordance with** the expedited review process [in accordance with] **at** N.J.A.C. 8:33-5.2, [along with] **and** a non-refundable application fee [in the amount] of \$7,500, [(within 30 days of the effective date of this rule)] **by September 16, 2015**.

2. – 3. (No change from proposal.)

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.-xv. (No change from proposal.)

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] **who shall initiate submission of data to the Data Monitor**[, and to the Department] **within 24 hours of procedure completion and complete such submission as promptly as possible** in accordance with N.J.A.C. 8:33E-1.9 and 2.10;

xvii. Report [adverse events, including] **to the Data Monitor, within 72 hours thereof, the occurrence of a** death[, the] **from any cause, a** need for emergency cardiac surgery, [or] **and** other events as **the Data Monitor** may [be identified by the Data Monitor, within one hour of occurrence to the Data Monitor]

identify, and, within seven days thereof, the occurrence of other adverse events such as recurrent myocardial infarction, stroke, bleeding, a need for vascular surgery or repair, unplanned cardiac catheterization, a subsequent PCI and/or CABG for any reason, or renal failure; and

xviii. (No change from proposal.)

5. Participating hospitals shall ensure that*[, before the commencement of diagnostic cardiac catheterization,]* each enrolled patient provides written informed consent ***pursuant to (c)6 below*** to participate in the State demonstration project ***[after receiving]* ***:

i. Before the commencement of diagnostic cardiac catheterization;

ii. After a patient has received primary PCI at a participating hospital and before the patient undergoes elective PCI at that hospital; or

iii. After a patient has received diagnostic cardiac catheterization at a non-participating hospital and before the patient undergoes elective PCI at a participating hospital;

6. Participating hospitals shall ensure that patients receive* the following information and an opportunity to review and consider such information ***before being asked to consent in writing to participate in the State demonstration project***:

i. –iii. (No change from proposal.)

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]* *(c)12*** below, or requires treatment that is not available at the participating hospital;

v. For ineligibility based on the reasons cited in **[(c)5iv]** **(c)6iv** above, a participating hospital would transfer an enrolled patient to a licensed cardiac surgery center for appropriate care; and

vi. (No change from proposal.)

Recodify proposed 6. and 7. as **7. and 8.** (No change in text from proposal.)

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

i.-iii. (No change from proposal.)

[9.] **10.** (No change in text from proposal.)

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

i.-ii. (No change from proposal.)

iii. High procedural risk as defined at **[(c)11]** **(c)12** below; or

iv. High likelihood of requiring a device that is not available at the participating hospital as defined at **[(c)12]** **(c)13** below.

Recodify proposed 11.-15. as **12.-16.** (No change in text from proposal.)

[16.] **17.** Notwithstanding (d)4 below, **and the Department's intention that** 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. – ii. (No change from proposal.)

(d) (No change from proposal.)