State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
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JON S. CORZINE
Governor

www.nj.gov/health

HEATHER HOWARD
Commissioner

November 10, 2008

VIA UNITED
PARCEL SERVICE

Deborah Zastocki
Chief Executive Officer
Chilton Memorial Hospital
97 West Parkway
Pompton Plains, New Jersey 07444-1697

Re: CN# FR 071225-14-01

Michael Maron
President and Chief Executive Officer
Holy Name Hospital
718 Teaneck Road
Teaneck, New Jersey 07666

Re: CN# FR 071213-02-01
Expiration Date: May 11, 2009

Daniel A. Kane
President and Chief Executive Officer
Bayonne Medical Center
29th Street at Avenue E
Bayonne, New Jersey 07002

Re: CN# FR 071226-09-01
Expiration Date: May 11, 2009

Peter Kelly
President and Chief Executive Officer
Christ Hospital
176 Palisade Avenue
Jersey City, New Jersey 07306

Re: CN# FR 071223-09-01

Thomas Biga
Chief Executive Officer
Clara Maass Medical Center
One Clara Maass Drive
Belleville, New Jersey 07109

Re: CN# FR 071217-07-01
Expiration Date: May 11, 2009

C. Barry Dykes
President and Chief Executive Officer
Mountainside Hospital
1 Bay Avenue
Montclair, New Jersey 07042

Re: CN# FR 071228-07-01

Gary S. Horan
President and Chief Executive Officer
Trinitas Hospital
225 Williamson Street
Elizabeth, New Jersey 07202

Re: CN# FR 071209-20-01
Expiration Date: May 11, 2009

Alan Lieber
Chief Operating Officer
Atlantic Health System
Overlook Hospital
99 Beauvoir Avenue
Summit, New Jersey 07902

Re: CN# FR 071220-20-01
Expiration Date: May 11, 2009

Leslie Hirsch
President and Chief Executive Officer
St. Clare's Hospital - Denville
25 Pocono Road
Denville, New Jersey 07843

Re: CN# FR 071210-14-01

Robert Wise
President and Chief Executive Officer
Hunterdon Medical Center
2100 Wescott Drive
Flemington, New Jersey 08822

Re: CN# FR 071219-10-01

John McGee
President and Chief Executive Officer
JFK Medical Center
65 James Street
P.O. Box 3059
Edison, New Jersey 08818

Re CN# FR 071215-12-01
Expiration Date: May 11, 2009

Michael R. D'Agnes
Chief Executive Officer
Raritan Bay Medical Center – Perth Amboy
530 New Brunswick Avenue
Perth Amboy, New Jersey 08861

Re: CN# FR 071228-07-01
Expiration Date: May 11, 2009

Alfred Glover
President and Chief Executive Officer
Saint Peter's University Hospital
254 Easton Avenue
P.O. Box 591
New Brunswick, New Jersey 08903

Re: CN# FR 071218-12-01

Kenneth Bateman
President and Chief Executive Officer
Somerset Medical Center
110 Rehill Road
Somerville, New Jersey 08876

Re: CN# FR 071222-18-01
Expiration Date: May 11, 2009

Barry Rabner
President and Chief Executive Officer
University Medical Center at Princeton
253 Witherspoon Street
Princeton, New Jersey 08540

Re: CN# FR 071208-11-01

Mark Pilla
Executive Director
Community Medical Center
99 Highway 37 West
Toms River, New Jersey 08755

Re: CN# FR 071220-15-01
Expiration Date: May 11, 2009

Frank J. Vozos, M.D.
Executive Director
Monmouth Medical Center
300 Second Avenue
Long Branch, New Jersey 07740

Re: CN# FR 071216-13-01

W. Peter Daniels
President and Chief Executive Officer
Ocean Medical Center
425 Jack Martin Boulevard
Bricktown, New Jersey 08724

Re: CN# FR 071231-15-01

Timothy J. Hogan
President
Riverview Medical Center
One Riverview Plaza
Red Bank, New Jersey 07701

Re: CN# FR 071221-13-01
Expiration Date: May 11, 2009

Al Maghazehe
Chief Executive Officer
Capital Health System - Mercer
446 Bellevue Avenue
Trenton, New Jersey 08618

Re: CN# FR 071211-11-01

Ellen Guarnieri
President and Chief Executive Officer

Robert Wood Johnson University
Hospital at Hamilton
One Hamilton Health Place
Hamilton, New Jersey 08690
Richard Miller
President and Chief Executive Officer

Re: CN# FR 071227-11-01
Expiration Date: May 11, 2009

Virtua-West Jersey Hospital Marlton
90 Brick Road
Marlton, New Jersey 08053

Re: CN# FR 071230-03-01
Expiration Date: May 11, 2009

Dear Ms. Zastocki, Mr. Maron, Mr. Kane, Mr. Kelly, Mr. Biga, Mr. Dykes, Mr. Horan, Mr. Lieber, Mr. Hirsch, Mr. Wise, Mr. McGee, Mr. D'Agnes, Mr. Glover, Mr. Bateman, Mr. Rabner, Mr. Pilla, Dr. Vozos, Mr. Daniels, Mr. Hogan, Mr. Maghazehe, Ms. Guarnieri, and Mr. Miller:

This letter sets forth the basis, rationale, and final decision in the matter of the Certificate of Need (CN) applications for participation in a demonstration project pertaining to elective angioplasty without back-up surgery on-site, 39 N.J.R. 4869(a) (November 5, 2007) (herein referred to as the "Call for Elective Angioplasty or PCI Demonstration Project" or "the Call"). I approve the following applications: Bayonne Medical Center (Bayonne), Clara Maass Medical Center (Clara Maass), Community Medical Center (Community), Holy Name Hospital (Holy Name), JFK Medical Center (JFK), Overlook Hospital (Overlook), Raritan Bay Medical Center (Raritan Bay), Riverview Medical Center (Riverview), Robert Wood Johnson University Medical Center at Hamilton (RWJ-Hamilton), Somerset Medical Center (Somerset), Trinitas Hospital (Trinitas) and Virtua West Jersey Hospital Marlton (Virtua-Marlton) (herein referred to as the "Demonstration Project Hospitals").

I do not approve the following applications: Capital Health System-Mercer (Capital-Mercer), Chilton Memorial Hospital (Chilton), Christ Hospital (Christ), Mountainside Hospital (Mountainside), St. Clare's Hospital-Denville (St. Clare's-Denville), Hunterdon Medical Center (Hunterdon), Monmouth Medical Center (Monmouth), Ocean Medical Center (Ocean), St. Peter's Medical Center (St. Peter's), and University Medical Center at Princeton (Princeton).

FACTUAL BACKGROUND: DEMONSTRATION PROJECT

N.J.A.C. 8:33-1.3 defines the term "demonstration project" as generally referring "to a health care service, technology, equipment, or modality not currently available in the State or which targets unique institutional circumstances or the needs of underserved populations." Although at least 20 other states[1] currently license this procedure, New Jersey does not provide licensure status for elective angioplasty without back-up surgery on-site. Therefore, the requirements for a demonstration project are met here because the provision of elective angioplasty services in facilities that do not have on-site cardiac surgery services is "not currently available in the State."

On October 31, 2005, nine hospitals were granted CN approval to participate in a demonstration project for elective angioplasty without on-site cardiac surgery back-up following a competitive full review CN process that included 18 CN applicants. The nine hospitals were licensed to perform elective coronary angioplasty without on-site cardiac surgery within six months of their respective CN approvals in the 2005 demonstration project. As a condition of CN approval, these nine hospitals in the 2005 demonstration project were limited to the performance of elective coronary angioplasty only on patients enrolled in the Atlantic Cardiovascular Patient Outcomes Research Team Trial-Elective Angioplasty Study [2] (Atlantic C-PORT-E or Atlantic C-PORT-E Study), led by Thomas Aversano, M.D., Johns Hopkins Medical Institutions. The Atlantic C-PORT-E Study is designed as a multi-state prospective, randomized trial, which is a scientifically rigorous form of a clinical trial, since the patients to be studied are assigned in advance, on a randomized basis, to have elective angioplasty either at the demonstration project hospital or a cardiac surgery center. [3] This type of design minimizes the potential for selection bias to influence the study outcomes. It also requires participating Demonstration Project Hospitals to adhere to strict patient selection and device inclusion/exclusion criteria and informed consent by patients in order to be enrolled in the Atlantic C-PORT-E Study.

The elective angioplasty demonstration project rule requires that all Demonstration Project Hospitals comply with all applicable licensure requirements (N.J.A.C. 8:33-3.11(e)6vi) and meet the inclusion criteria specified in the Atlantic C-PORT-E Study. The Manual of Operations identifies the oversight committees designed to ensure the integrity and safety of the Atlantic C-PORT-E Study and to identify and remediate potential errors as quickly as possible. As noted in a response to comments, “The Manual of Operations recognizes that "continued inclusion of a participating hospital in the C-PORT study requires adherence to the spirit and letter of state health-care regulation[. R]egular reporting of the course of the Atlantic C-PORT-E Study, including adherence to the terms and conditions of the granted waiver, will be made to the Department of Health of each state in which there are participating sites." If the Department were to receive information from the principal investigator that a facility's continued participation in the demonstration project would be violative of the licensure requirements or otherwise inappropriate, the Department would take appropriate administrative measures in accordance with applicable licensure standards. At the same time, the Department monitors volume and other indicia relating to the quality of all cardiac care patients through the cardiac data reporting and through measures applicable to all licensed healthcare facilities to ensure patient safety.” [4] Thus, once appropriate demonstration project sites are selected, data collection relevant to the Atlantic C-PORT-E Study is the responsibility of the principal investigator. At the same time, the Department continues to maintain its commitment and obligation to enforce licensure standards and to ensure patient safety through existing reporting and oversight measures applicable to licensed healthcare facilities generally and to cardiac care facilities specifically.

The Department is satisfied that the demonstration project’s licensing controls established by administrative rule, and with the principal investigator's compliance with

the Johns Hopkins Institutional Review Board (IRB) process and that IRB's approval of the Atlantic C-PORT-E Manual of Operations provides appropriate oversight and monitoring. Each New Jersey facility participating in the demonstration project agrees to meet the required licensing standards, receive approval from the participating hospital's IRB, and adhere to the Atlantic C-PORT-E Study's Manual of Operations. [5]

The nine demonstration project hospitals began enrolling patients in the Atlantic C-PORT-E study between April 19, 2006 and June 27, 2006. The nine demonstraton project hospitals have enrolled a total of 2,188 patients as of June 24, 2008 representing 26 percent of all patients enrolled in the Atlantic C-PORT-E Study.

On May 31, 2007, in *Cooper University Hospital v. Jacobs 191 N.J. 125 (2007),* the New Jersey Supreme Court found invalid the Department's process for the issuance of certificates of need to perform elective angioplasty or PCI without on-site cardiac surgery backup as part of New Jersey's participation in the Atlantic C-PORT-E Study. In response to the Supreme Court's decision in *Cooper University Hospital v. Jacobs*, the Department adopted administrative rules specific to the elective angioplasty demonstration project pertaining to elective angioplasty at N.J.A.C. 8:33-3.11(e), and published a CN call notice for the submission of demonstration project applications.

As both the Department's original November 1, 2004 Call Notice [6] and subsequent November 5, 2007 Call Notice [7] indicated, the Department has taken these elective angioplasty demonstration project CN actions as part of a broader cardiovascular health initiative. The Department's Cardiovascular Health Advisory Panel stated its support of research and clinical improvements in recommending that the Department participate in the demonstration project. The purpose of the demonstration project pertaining to elective angioplasty is to authorize New Jersey hospitals to participate in the Hopkins-led study to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty in hospitals with and without on-site coronary artery bypass graft (CABG) surgical back-up.

Clinical studies and trials are part of a long, careful research process and throughout the State, patients, physicians and New Jersey hospitals are participating in a wide-range of clinical trials. New Jersey, as a densely populated and diverse State, has much to offer and much to gain from participating in clinical trials such as the Atlantic C-PORT-E Study. The State offers a sizable number of patients to contribute to the Atlantic C-PORT-E Study which will help the study to achieve its volume goals more efficiently. At the same time, the Atlantic C-PORT-E Study results would inform the State's policy determinations with respect to the safety and efficacy of elective PCI without on-site cardiac surgery under the conditions the demonstration project establishes. The Atlantic C-PORT-E Study results would inform policymakers with respect to future resource allocation that may enhance access to elective angioplasty for New Jersey residents in urban, rural, and suburban hospitals.

As set forth in the November 5, 2007 Call Notice, the submission of CN applications was limited to eligible licensed general hospitals. Prior to the issuance of this Call Notice, and in response to the decision of the New Jersey Supreme Court in *Cooper University Hospital v. Jacobs, 191 N.J. 125 (2007*), the Department established CN eligibility and review criteria for elective angioplasty demonstration projects through the administrative rule-making process. See 39 N.J.R. 3462(a), 39 N.J.R. 5316(b)) as set forth at N.J.A.C. 8:33-3.11(e). The November 5, 2007 Call Notice therefore also required hospitals to document compliance with the newly adopted administrative rules related to CN eligibility and review criteria for the elective angioplasty demonstration project.

The Department had indicated in both the 2005 and current CN review processes for the elective angioplasty demonstration project that there was very strong interest from a number of New Jersey hospitals in offering elective angioplasty services, independent of offering cardiac surgery at the same site. This was confirmed by the fact that the Department received a total of 25 certificate of need applications for the elective angioplasty demonstration project in the current call and 18 in the previous 2005 call. This continued interest was motivated, at least in part, by the statewide trends for declining demand for cardiac surgery and increasing demand for coronary angioplasty or PCI over a period of time (2000 – 2006).[8]

As Department staff noted in their elective angioplasty demonstration project recommendations, the decline in angioplasty or PCI volume statewide in 2007 can be attributed, at least in part, to evidence from clinical trials that PCI may not be superior to optimal medical therapy in reducing the risk of death or myocardial infarction. It is also important to note that there have been years during the past two decades that cardiac interventions have exhibited a decline, and that have been followed by continued growth. This may very well be the case with regard to calendar year 2007 cardiac procedure levels, particularly considering the fact that annualizing first and second quarter 2008 statewide PCI data (13,003 cases) would result in a 1.0 percent increase over 2007. By the same token, annualizing first and second quarter 2008 statewide diagnostic cardiac catheterization cases (36,179 cases) would similarly result in a slight increase over 2007. I agree with staff that it would therefore be inappropriate and premature to project long-term trends based on a single calendar year (2007), as some affected parties had suggested in their public testimony at the State Health Planning Board meeting. It is reasonable for the State to participate in the controlled Hopkins-led study, Atlantic C-PORT-E Study, to determine if there is adequate evidence that the American College of Cardiology/American Heart Association (hereinafter referred to as "ACC/AHA") and states, including New Jersey, should consider in evaluating whether to change CN and licensure policy linking elective angioplasty and cardiac surgery.

The participation of New Jersey hospitals in the Atlantic C-PORT-E Study will help to enhance facility and practitioner experience in the procedure, thereby facilitating patient access should the State ultimately determine to make the procedure a regular licensed service. However, significant public discussion concerning any future

amendments to hospital-based cardiac services specifically as it relates to elective angioplasty without back-up surgery on-site would occur prior to any determination to make the procedure a licensed service. This discussion will no doubt include analysis of the relative safety and efficacy of the provision of elective angioplasty in various circumstances and the significant issue of the important link between procedure volume and quality. It bears repeating that there is no relationship between participation in the demonstration project and which hospitals, if any, would be granted licensure for this procedure should the Department amend its administrative rules in the future to allow licensure for elective angioplasty without on-site cardiac surgery back-up.

At present, there continues to be little sound research data available on the issue of the comparative safety of elective angioplasty at hospitals without on-site cardiac surgery back-up. Without research findings on this issue, there is little scientific basis on which the ACC/AHA could rely in considering changes to the current guidelines that call for elective angioplasty to be performed in hospitals with cardiac surgery on-site. The Department has relied to a great extent in developing its standards for hospital-based cardiac services on the clinical guidelines developed by the ACC/AHA. When the ACC/AHA guidelines concerning primary angioplasty were modified, after review of newer research comparing favorably the safety of these services in hospitals with and without cardiac surgery on-site, the Department subsequently modified the CN rules to uncouple primary angioplasty from on-site cardiac surgery. Although many states allow elective angioplasty without back-up surgery on-site through routine licensure processes, there continues to be inadequate evidence that the Department could consider in evaluating whether to change its CN and licensure policy linking elective angioplasty and cardiac surgery, despite the widespread interest of hospitals, cardiologists, and consumers in making this service widely available in community hospitals, rather than limited, as at present, to tertiary-level hospitals.

It is in this context, coupled with the Department's need to respond to the public interest in expanding the availability of elective angioplasty in New Jersey, that the Department determined to contribute to the effort to create an objective basis for assessing this issue by calling for a demonstration project "to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty in hospitals with and without on-site coronary artery bypass graft (CABG) surgical back up." To ensure that the demonstration project would yield "sound data and evidence," the Department specifically requested in the Nov. 1, 2004 Call Notice and the Nov. 5, 2007 Call Notice "applications for participation in a planned multi-state, prospective, randomized elective angioplasty trial, The Atlantic C-PORT Trial, Elective Angioplasty Study, Randomized Study of Non-emergency Percutaneous Coronary Intervention (PCI) in Hospitals with and without On-Site Cardiac Surgery (Atlantic C-PORT-E)."

As additional background, Thomas Aversano, M.D., Associate Professor of Medicine, Johns Hopkins Medical Institutions and Director of the Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-PORT) was the lead author of

"Thrombolytic Therapy vs. Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery: A Randomized Controlled Trial", published in the Journal of the American Medical Association in 2002.[9] The research findings underlying this publication contributed significantly to the revised ACC/AHA guidelines concerning primary, or emergency, angioplasty.

Dr. Aversano's Atlantic C-PORT-E Study is designed to assess: "1. Can [elective] PCI be performed safely and effectively at hospitals without SOS [surgery on site]? 2. Under what conditions is this possible?" More specifically, "This study tests the hypothesis that outcomes of elective PCI performed at hospitals without SOS are not inferior to outcomes of PCI performed at hospitals with SOS …the primary endpoint is mortality 6 weeks after index PCI."[10] Additional outcomes data will also be collected and analyzed, including the comparative incidence of heart attack, stroke, bleeding, heart failure, and target vessel revascularization; comparative incidence and classification of heart failure and angina; comparative angiographic and clinical success rates; and the comparative cost of care. The cost comparison will be conducted by a team from Duke University; otherwise, the Johns Hopkins Medical Institutions serves as the Study's Clinical Coordinating Center.

As indicated in Department staff recommendations, the Atlantic C-PORT-E Study is designed to be multi-state, and requires enrollment of approximately 18,360 patients over a several year period in order to achieve sufficient statistical power to produce meaningful results. Dr. Aversano's protocol provides for informed consent by patients before they can be enrolled in the study; both Dr. Aversano and the Department require, and will continue to require, each Demonstration Project Hospital to secure approval from its Institutional Review Board for its participation in this study involving human subjects. As of the date of preparation of the staff recommendations, Dr. Aversano advised that the following states were participating in Atlantic C-PORT-E, in addition to the nine demonstration sites in New Jersey: Georgia, Ohio, Texas, North Carolina, Illinois, Alabama, Pennsylvania, Maryland and Oregon. When Atlantic C-PORT-E Study enrollment is reached, New Jersey's demonstration project will cease as will the authorization to perform elective angioplasty without back-up surgery on-site. At that time, each Demonstration Project Hospital shall return its license to perform elective angioplasty and discontinue this service.

Consistent with the previous primary angioplasty study protocol, Atlantic C-PORT-E contains rigorous criteria governing matters such as patient eligibility, inclusion criteria of participating hospitals, as well as the physicians performing the elective angioplasty procedures, device inclusion/exclusion criteria, etc. The Department's rules for this demonstration project, as set forth at N.J.A.C. 8:33-3.11(e), incorporated by reference all of the Atlantic C-PORT-E protocol requirements for participating hospitals. As a further safeguard, each demonstration project hospital must seek approval from its Institutional Review Board, adding another level of reporting and review. It is particularly important to note that, if study enrollment is stopped early because the early

evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well.

Consistent with its regulatory authority, the Department annually evaluates all licensed cardiac service providers for compliance with existing licensing requirements for cardiac services at N.J.A.C. 8:33E and 8:43G-7. In addition, the Department responds to complaints of its licensed cardiac services just as it does for all other licensed health care. Consistent with these licensing rules, the Department includes facility and physician performance criteria in its annual cardiac licensure reviews, which it conducts concurrently with the review of the hospital prior to its licensure anniversary date. N.J.A.C. 8:33E-1.13 and 2.13 establish procedures to which the Department adheres in addressing non-compliant cardiac services. These rules require, among other measures, external review by an independent external organization the Department approves, to assess the overall performance of the facility and its staff, a detailed plan of correction to ensure that a non-compliant facility implements corrective action to achieve compliance, and the articulation of a date by which a noncompliant facility will reach compliance with applicable licensure standards. In the past, the Department has worked closely with cardiac centers operating on conditional licenses pending full compliance with volume requirements.

The Department's elective angioplasty demonstration project rules specifically limit the performance of elective angioplasty to patients enrolled in the Atlantic C-PORT-E Study (N.J.A.C. 8:33-3.11(e)5i). Moreover, should the Atlantic C-PORT-E Study be halted prior to its anticipated conclusion, in accordance with the Study's stopping rules, all demonstration licenses issued in connection with this Study will be terminated no later than 30 days after Atlantic C-PORT-E is halted (N.J.A.C. 8:33-3.11(e)5iv). Thus, the Department's elective angioplasty demonstration project rules provide assurance that if Study enrollment were to be stopped early because early evidence convincingly indicated safety problems, the State's demonstration project would also be terminated. The Atlantic C-PORT-E Study is closely monitored by Johns Hopkins Medical Institutions. A Data Monitoring and Safety Board reviews the study and has the authority to recommend suspension of the study or any other action it deems necessary in response to an event. On June 19, 2008, the letter from the Data Monitoring and Safety Board stating its "unanimous and enthusiastic continuation of the study" was submitted to the SHPB as part of its review materials. Dr. Aversano has also stated that the Atlantic C-PORT-E Study's DSMB discussed recent reports from the Mayo Clinic and the American College of Cardiology National Cardiovascular Data Registry indicating that elective PCI without on-site cardiac surgery can be performed safely. Such reports, while no doubt encouraging, represent registry reports and not the more scientifically rigorous randomized trial that is being undertaken as the Atlantic C-PORT-E study.

In response to the Nov. 5, 2007 Notice Of Invitation For Certificate Of Need Applications For Participation In A Demonstration Project Pertaining To Elective Angioplasty Without Back-Up Surgery, a total of 25 CN applications were submitted by December 18, 2007, by Bayonne, Capital-Mercer, Christ, Chilton, Clara Maass,

Community, Holy Name, Hunterdon, JFK, Monmouth, Mountainside, Muhlenberg, Ocean, Overlook, Princeton, Raritan Bay, Riverview, RWJ-Hamilton, St. Clare's, St. Peter's, Somerset, South Jersey, Trinitas, Virtua – Burlington and Virtua – Marlton. All but one of the 25 CN demonstration project applicants were determined to be in compliance with the eligibility requirements specified above. On January 17, 2008, South Jersey Regional Medical Center was notified by the Department that it had failed to document compliance with the submission eligibility requirements set forth in the November 5, 2007 CN Call and at N.J.A.C. 8:33-3.11(e)4. On February 15, 2008, the Department declared the remaining 24 CN demonstration project applications complete. On March 3, 2008, Muhlenberg Regional Medical Center, one of the current participants in the Atlantic C-PORT-E Study, provided written notification to the Department that it was necessary to withdraw its CN application for the elective angioplasty demonstration project in light of Solaris Health System's filing of a CN to close Muhlenberg Regional Medical Center. On April 3, 2008, Virtua Memorial Hospital of Burlington County provided written notification to the Department that it was withdrawing its CN application to rationalize Virtua Health services and resources as a system, since its highest priority is "to continue participation in the demonstration project at our Marlton Hospital." As a result of these events, a total of 22 demonstration project CN applications are eligible for review.

The Department obtained public input into the review process by accepting public comment on the Notice Of Invitation For Certificate Of Need Applications For Participation In A Demonstration Project Pertaining To Elective Angioplasty Without Back-Up Surgery On-Site applications both as written comments prior to and as testimony at the State Health Planning Board meeting held on July 10, 2008. In advance of their deliberations on the 22 applications, the Department provided SHPB members with complete copies of each CN application, completeness questions and answers, written material submitted by various members of the public, as well as review materials prepared by Department staff and recommendations on each application from Department staff (staff recommendations), which constituted the record of the SHPB meeting. After the SHPB meeting, staff forwarded the SHPB transcript and record on this Call to me, for my independent review and rendering of the agency decision.

Certificate of Need Review Criteria

With respect to the statutory CN review criteria, N.J.S.A. 26:2H-8 provides for the issuance of a CN only where the action proposed in the application for such certificate is necessary to provide required health care in the area to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health services in the region or statewide, and will contribute to the orderly development of adequate and effective health care services. In making such determinations, I must take into consideration: a) the availability of facilities or services that may serve as alternatives or substitutes, b) the need for special equipment and services in the area, c) the possible economies and improvement in services to be anticipated from the operation of joint central services, d) the adequacy of financial resources and sources of present and future revenues, e) the availability of sufficient

workforce in the several professional disciplines, and f) such other factors as may be established by regulation.

With respect to the latter consideration, I am required to consider whether each applicant has sufficiently documented the ability to satisfy specific elective angioplasty demonstration project criteria at N.J.A.C. 8:33-3.11(e), including: documentation of the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization[11], as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

I am also required to consider whether each applicant has sufficiently documented the ability to satisfy the Atlantic C-PORT-E Study site inclusion criteria specified in the Atlantic C-PORT-E protocol, including: (1) capability of performing a minimum volume of diagnostic cardiac catheterizations per year (N.J.A.C. 8:33-3.11(e)6i(1)); (2) agreement to complete an elective PCI development program (N.J.A.C. 8:33-3.11(e)6i(2)); (3) agreement to abide by physician, patient and device selection criteria defined in the Study's Manual of Operations (N.J.A.C. 8:33-3.11(e)6i(3)); (4) agreement to collect and transmit study data in a timely fashion (N.J.A.C. 8:33-3.11(e)6i(4)); (5) agreement to perform elective PCI only via the study protocol and only while cases are being enrolled in the Study (N.J.A.C. 8:33-3.11(e)6i(5)); and (6) agreement to develop and maintain a quality and error management program, including a weekly interventional conference and monthly quality and error management review (N.J.A.C. 8:33-3.11(e)6i(6)).

Because this is a demonstration project, the Department limited certificate of need approval to up to 12 applications and articulated additional competitive review criteria at N.J.A.C. 8:33-3.11(e)7, as follows: a) the applicant's ability to offer a high quality program; b) the applicant's ability to provide patient selection from a community that is representative of the State's diverse regions and urban, suburban, and/or rural populations; c) potential to increase access to care for minorities and the medically underserved by selection of the applicant; and d) the applicant's ability to achieve projected demonstration project elective PCI case volume by selection.

FINDINGS

In reaching my decision on each application I have considered: the review criteria articulated in the Call for Elective Angioplasty Demonstration Project; the administrative rules recently promulgated for the elective angioplasty demonstration projects as set forth at N.J.A.C. 8:33-3.11(e); the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1.1 et seq.), as amended; the CN administrative process rules as set forth at N.J.A.C. 8:33; the cardiac services licensure rules as set forth in both N.J.A.C. 8:33E and N.J.A.C. 8:43G, the most recently available Statewide and region-specific cardiac service utilization data; PCI and diagnostic cardiac catheterization outcomes; and population/demographic data. I carefully reviewed the information provided in each, the Atlantic C-PORT-E Study protocol, and the Transcript of July 10, 2008 SHPB Proceeding, which included the SHPB recommendations.

In my consideration of the Call, I find it reasonable to incorporate into my decision-making recognition of the activities of the Department and the principal public health policy issues affecting the State. N.J.S.A. 26:1A-3. In support of my findings, I find the Department's public notice of proposal and adoption of administrative rules relating to elective angioplasty demonstration projects at N.J.A.C. 8:33-3.11(e) and the Call itself are within statutory authority. This Call is consistent with N.J.A.C. 8:33-3.11(e), which has been adopted to detail the requirements of an elective angioplasty demonstration project. Furthermore, N.J.S.A. 26:2H-5.8(b) specifically states that the SHPB shall make recommendations to the Commissioner. The findings are consistent with my review of the record, and my understanding of the public interest in the State's participation in Atlantic C-Port-E to develop evidence that could benefit cardiac patients.

The Department staff recommended nine applications to the SHPB. The SHPB, at its July 10, 2008 meeting, recommended approval of the "maximum of twelve applications" pursuant to the Call and N.J.A.C. 8:33-3.11(e)7.

GENERAL FINDINGS

I find the need for continuation of this time-limited demonstration project and participation in the Atlantic C-PORT-E Study remains valid and reasonable, and that it is appropriate to approve 12 of the remaining 22 applicants. This finding is consistent with former Commissioner Jacobs' determination that a greater number of participating hospitals would be beneficial to the success of the Study specifically that the participation of a larger number of Demonstration Project Hospitals would be likely to generate more patients that could be enrolled in the Study in a timely manner. The State Health Planning Board recommended 12 demonstration project hospitals to provide some cushion for unanticipated circumstances that could result in a hospital failing to enroll in Atlantic C-PORT-E, or having to drop out of the demonstration project early.

All of the applicants were able to demonstrate compliance with most of the review criteria, and many applications were of very high quality. While I understand that

the Department staff, in making their recommendation to approve only nine applications, felt constrained to stay well within the Call's expressed maximum of 12 applications to recommend for approval, I find sufficient reason to agree with the SHPB and increase this number from nine to twelve. The limitation on the number of demonstration projects represented an attempt to balance competing perspectives about the need for the Call to generate a sufficient contribution of cases to the multi-state study with anticipated concerns that the Study might create an impression that it was a vehicle for widespread proliferation of elective angioplasty without on-site cardiac surgical back-up. As the staff recommendations state, the elective angioplasty demonstration project rules, as set forth at N.J.A.C. 8:33-3.11(e), explicitly prohibit the performance of elective angioplasty by a hospital without on-site surgical back-up on any patient not enrolled in the Atlantic C-PORT-E Study. Since patients must give informed consent prior to being enrolled in Atlantic C-PORT-E, including their agreement to allow the central Study managers to randomly assign them to have their procedure performed either at the Demonstration Project Hospital or a cardiac surgery center, it is reasonable to expect that a number of patients will not consent to participation in the Study. The enrollment data from New Jersey's current nine demonstration project hospitals document a lower enrollment rate than that projected by the Atlantic C-PORT-E Study (i.e., 30 percent) and by many, if not all, of the participating demonstration project hospitals. The enrollment of 1,201 patients in the Atlantic C-PORT-E Study in the first full year of New Jersey hospital participation, with 900 of these enrollees receiving their elective angioplasty procedure at the 9 demonstration project hospitals, represent 5.2 percent of total elective angioplasty cases performed in New Jersey in 2007 with only 3.9 percent performed at the demonstration project hospitals. The approval of 12 Demonstration Project Hospitals, therefore, will allow for the timely completion of the study by high quality programs, diverse representation across the State, and improve access to minority and medically underserved populations, with a minimal impact on the existing providers. I concur with the staff analysis that opponents of this latest Call have greatly overstated the potential for the demonstration project hospitals to reduce elective angioplasty volume at existing service providers in a way that meets the statutory criterion of having an adverse financial or economic impact on the delivery of health services in a region or Statewide. This is particularly the case since these CN approvals, in accordance with N.J.A.C. 8:33-3.11(e)3, are of limited duration and the demand for elective angioplasty in New Jersey has shown signs of recovering from a brief one-year decline. Dr. Aversano provided an update on Atlantic C-PORT-E Study progress to the SHPB and indicated that it was his expectation that, even without adding any additional sites, the study can be completed in 36 months provided current enrollment rates were maintained. It was also his expectation that the addition of sites in Maryland and Pennsylvania would hasten the study's completion by up to 12 months.

I am also satisfied that Atlantic C-PORT-E contains rigorous criteria governing matters such as patient eligibility, inclusion criteria of participating demonstration project hospitals, as well as the physicians performing the elective angioplasty procedures, and, device inclusion/exclusion criteria, etc. The Study has gone through the Johns Hopkins Institutional Review Board and has been submitted or will be submitted to every Demonstration Project Hospital's Institutional Review Board for review.

Based on these reasons, I find that it is both reasonable and appropriate to approve 12 of the 22 remaining applications submitted for participation in the Call. While I agree with the staff analysis as to which review criteria show the most variability among applicants, I find the rationale and conclusions reached by the SHPB in recommending three additional demonstration project hospitals to be persuasive.

Ability to offer a high quality program (N.J.A.C. 8:33-3.11(e)7i.)

In my judgment, a facility's ability to offer a high-quality program is one of the most important criteria to focus on, but also one of the most difficult to assess, particularly in appropriate, readily quantifiable and objective terms. In its independent analysis, Department staff reviewed each applicant's historic and current track record of compliance with licensure requirements for the existing cardiac services provided by each applicant (that is, cardiac catheterization and primary PCI, if applicable). Staff also reviewed the applicant's historical outcomes, such as death in lab, death in hospital and all in-lab complications of each applicant's diagnostic cardiac catheterization program. Staff also reviewed the number of interventional cardiologists on each applicant's staff and their respective performance in terms of interventional case volume.

I note that the review of each applicant's historic and current track record of compliance with existing cardiac services cannot be uniformly applied nor can the conditional or unconditional licensure of a cardiac service be directly related to patient outcome measures. This is particularly important since mortality and complications resulting from cardiac catheterization and, less so, from coronary angioplasty are relatively rare events. Under the Department's cardiac licensing authority, a conditional licensure determination also carries with it the requirement to submit an acceptable plan of correction and undergo an external review of the overall quality of their program by an independent third party clinical cardiac expert as set forth at N.J.A.C. 8:33E-1.13(d). Therefore, although I have considered this information during my review, I have generally given it less weight in my deliberations than did the staff.

Representation of the State's diverse regions and urban/suburban/rural populations (N.J.A.C. 8:33-3.11(e)7ii.)

The 22 remaining demonstration applicants are located in 12 of the State's 21 counties. A total of six of the 22 demonstration project applicants are located in four counties (i.e., Hunterdon, Ocean, Somerset, Union) that do not have a cardiac surgery center providing elective angioplasty located within that county. While in each case elective angioplasty services are available in contiguous counties, 100 percent of patients residing in these 4 counties who are in need of elective angioplasty would be required to leave the county to receive the service. Two of these four counties, Somerset and Union, currently have elective angioplasty demonstration project hospitals in the Atlantic C-PORT-E Study and these hospitals were seeking continued participation in this review process.

In addition, Department staff considered each applicant's location based on the eight defined geographic areas ("hospital market areas") that the New Jersey Commission on Rationalizing Health Care Resources[12] (the "Commission") determined to be reflective of actual patient utilization of hospitals. The 22 elective angioplasty demonstration project hospital applicants are located in seven of the Commission's eight distinct hospital market areas that the Commission concluded reflect the natural market areas where New Jersey residents receive inpatient care. The Commission considered these areas to be appropriately defined geographic areas for the purposes of their analysis and Department staff also considered these areas to be appropriate for this review process as well. In considering the need for representation of the State's diverse regions and urban, suburban, and rural populations**,** I am also acutely aware of the need to preserve health care access in urban areas. Yet, participation in the demonstration project does not equate to a permanent change to licensed health services and as noted, above, the enrollment at the initial 9 demonstration project hospitals, represents 5.2 percent of total elective angioplasty cases performed in New Jersey in 2007 with only 3.9 percent performed at the demonstration project hospitals. And on balance, there continues to be inadequate evidence that the Department could consider in evaluating whether to change its CN and licensure policy, after public discussion, linking elective angioplasty and cardiac surgery, despite the widespread interest of hospitals, cardiologists, and consumers in making this service widely available in community hospitals, rather than limited, as at present, to tertiary-level hospitals. As such, demonstration project hospitals must represent the unique geography of the State and suburban, rural and urban hospitals are included in the Atlantic C-PORT-E Study. It is reasonable for the State to participate in this Study.

While I concur with Department staff that the New Jersey Commission on Rationalizing Health Care Resources' regions are appropriate for this review process, I find that the nine applicants recommended by staff do not sufficiently represent the diverse regions of this State, particularly the Northeastern region, which is also the State's most densely populated region. In making my decision, I have corrected this imbalance, which is consistent with the recommendations of the SHPB.

Potential to increase access to care for minorities and the medically underserved (N.J.A.C. 8:33-3.11(e)7iii.)

Department staff reviewed the extent that medically underserved and minority populations within each applicant's service area are able to access current cardiac services provided by the Call applicants, as well as the variation among applicants in the racial/ethnic composition of their service areas. This was accomplished by analyzing the racial/ethnic composition of the patient population in the service area and among those receiving diagnostic cardiac catheterization at the applicant's facility. Applicants ranged from having a three percent to 71 percent minority share of their diagnostic caseload. I found this data to provide one of the most compelling ways to differentiate the relative merits of the applicants and have weighed this factor heavily in my decision. When forced to choose, for example, between a record of high volume and a record of serving a higher proportion of minority and

medically underserved patients, I have generally decided in favor of increasing minority access.

Projected demonstration project elective angioplasty case volume (N.J.A.C. 8:33-3.11(e)7iv.)

The Department staff reviewed the historical utilization of the diagnostic cardiac catheterization services provided by the demonstration project applicants and evaluated potential elective angioplasty (PCI) case volume based on the Manual of Operations' projected diagnostic cardiac catheterization to elective angioplasty conversion rate of 30 percent. This potential PCI volume was then compared to the Department's minimum annual volume requirement for the performance of elective angioplasty demonstration projects set forth at N.J.A.C. 8:33-3.11(e)6v. This volume level is consistent with the Atlantic C-PORT-E Manual of Operations or Study protocol that anticipates that each demonstration site will perform a total of 200 primary and elective angioplasties per year.[13]

When considering applicants' current diagnostic and primary PCI case volume, as well as the number of cases randomized to have PCI at a cardiac surgery center (25 percent),[14] staff concluded that nine hospitals would likely meet the target in the first year of operation. Each applicant shall be conditioned to meet the target facility volumes of both Department licensure standards and the Atlantic C-PORT-E protocol. However, I believe that comparatively small differences among some applicants may have played a disproportionate role in shaping the staff recommendations.

I also believe that physician recruitment can dramatically impact on an applicant's potential facility volume. Many applicants presented statements by physicians practicing in their labs to the effect that, with approval to participate in the Atlantic C-PORT-E Study, they would recommend enrollment in the Study to a number of their patients who would currently have elective angioplasty procedures performed by these same physicians in cardiac surgery centers. While not all patients who receive such a recommendation would be likely to agree to participate in the Study, I am persuaded that a number of them would choose to participate after consultation with their practitioner. I find convincing the argument that cardiologists routinely route patients for whom they anticipate that a diagnostic catheterization study will provide clear indication of a need for an intervention to the cardiac surgery centers where elective angioplasty is permitted. This is particularly likely if the cardiologists utilize the so-called look-see approach, in which a diagnostic and an interventional catheterization are performed sequentially, but in the same catheterization laboratory session, saving the patient two trips to the lab for separate procedures.

I find, therefore, that the staff analysis tended to understate to some degree the likely projected volume for each applicant in assessing the applicants' ability to satisfy the 200 cases/year standard. However, I further find that, where a lower volume applicant was not exceptionally strong on any of the other review criteria, higher volume applicants are deserving of preference.

Adverse economic or financial impact on delivery of health care services in the region and Statewide; contribute to orderly development of adequate and effective health care services

Regardless of whether New Jersey hospitals participate in the demonstration project, a successful multi-state trial may ultimately result in the Department changing its administrative rules to permit elective PCI without cardiac surgery backup on-site. A change to the administrative rules would occur after significant public discussion and comment. Hospitals being confronted by an increased number of in-state competitors providing elective angioplasty would, in that case, be inevitable, although the question of the financial harm each hospital might suffer would depend on its ability to compete successfully to retain its current market share for elective angioplasty in the region, as well as on the rate of growth in demand for elective angioplasty.

As to this decision, I am not satisfied that any resulting financial detriment to any hospital would be so much attributable to the approval of the time limited demonstration project CN awards as it would be attributable to the declining use of cardiac surgery generally and the increasing safety of the angioplasty procedures that substitute for certain cardiac surgery procedures. It is not the Department's regulatory role to protect a facility in light of that facility's failure to anticipate, adapt to change or its ability to continue to provide a licensed service that market forces and scientific advances may indicate should be widely available and accessible rather than concentrated among a few providers. As noted in the Final Report of the Commission on Rationalizing Health Care Resources, a hospital's financial condition is dependent on a number of diverse factors including, but not limited to, payer mix, services, management practices, governance, and excess capacity in the market area. Dependency on any particular treatment, especially in light of the rapid change in medical technology, is a major risk factor for a hospital's financial condition.

The record of the SHPB meeting and the materials submitted to the SHPB in advance of the meeting indicate that some existing cardiac surgery centers oppose allowing any New Jersey community hospitals to participate in Atlantic C-PORT-E, because they view any potential resulting reduction in their own angioplasty volume as harmful. As stated earlier, as an across-the-board judgment on every application, this assessment is not well founded. Angioplasty volume in New Jersey, while experiencing a sharp decline during calendar year 2007, appears to give indication of leveling off in 2008 based on preliminary figures for the first quarter. Moreover, under the terms of the Atlantic C-PORT-E protocol, not every candidate for elective angioplasty would also be eligible to participate in the Study. Furthermore, it cannot be presumed that every eligible patient will consent to participate in the Study. Since Demonstration Project Hospitals will be permitted to perform elective angioplasty only on patients enrolled in the Study, the adverse financial impact the Study sites will have on existing providers of cardiac services is likely to be limited and of little significance. I believe competition, particularly when it is competition based on studied clinical evidence and quality of care, can be a positive force for expanding access and enhancing services to patients.

In reviewing the Atlantic C-PORT-E Study enrollment data for the nine participating New Jersey hospitals in calendar year 2007, the total enrollment of 1201 patients, that is 901 patients receiving PCI at the demonstration sites and 300 randomized to participating cardiac surgery centers, amounted to 5.2 percent of total elective angioplasty cases in New Jersey. More specifically, the 901 elective angioplasty cases performed at the nine demonstration project hospitals amounted to only 3.9 percent of the State's elective angioplasty cases in 2007.

I find that, in view of the very strong public and provider interest in making elective angioplasty widely available in community hospitals throughout the State, the orderly development of adequate and effective health care services demands that the Department develop a response to this interest that is based on sound evidence on the safety of elective angioplasty in a community hospital setting. It is also important to note that the Department's historic emphasis on the need to ensure access to cardiac services for the minority and medically underserved populations is based on the need to avoid equating capacity with accessibility. As the cardiac literature indicates, some populations appear to experience functional barriers to access to care when services are regionalized, and the question should be posed as to whether excellence should be concentrated or dispersed widely. Unlike cardiac surgery, where demand is declining and there is a need to keep this service regionalized to maintain sufficient volume to achieve high quality of care, the demand for elective angioplasty, if not exhibiting the growth that it has in the past, remains considerably larger. If the demand trend for elective angioplasty is regained and the Study provides evidence that this procedure may be provided safely in a community hospital setting with appropriate licensing standards, then there would be an argument for the Department to adopt this service, just as it did in 2001 when it adopted rules that make it possible for many community hospitals to provide life-saving emergency angioplasty to heart attack victims. The demonstration project would generate the data that would enable the Department to evaluate the efficacy of the procedure in making public policy determinations as to whether to authorize the procedure as a regular licensed procedure in the ordinary course.[15] I also note the difficulty hospitals have in supporting an emergency angioplasty program on a stand-alone basis.[16] Emergency angioplasty has a comparatively small volume but high fixed costs, particularly given the strict quality standards imposed by New Jersey's licensure standards for such programs. It may well be that, over the longer term, the continued viability of emergency angioplasty programs may depend on their being coupled with safe elective angioplasty programs. Given this concern, and with the leading professional societies involved in cardiac care all indicating a dearth of sound evidence on precisely whether and under what conditions elective angioplasty can be safety offered in a setting without on-site cardiac surgery, it is incumbent upon the Department to make every effort to contribute to the development of such evidence.

The staff and SHPB recommendations rely heavily upon the fact that a number of applicants are located in four counties that do not currently have a provider of elective angioplasty. Although I generally concur with this emphasis, I find that it can, in some

instances, be outweighed by the evidence concerning an applicant's service to minorities and the medically underserved.

In evaluating each applicant according to these review criteria, I, like the Department staff and the SHPB, have had to balance the review criteria, because relatively few of the applicants were able to sustain high rankings in all of the evaluative areas. For example, an applicant might rank comparatively lower in volume, but rank comparatively higher in enhancing minority or medically underserved access, in achieving high quality outcome measures, or in representing diverse regions of the State. Although the way in which I have measured the applicants against these criteria differs somewhat from the approach taken by Department staff, in nine of twelve cases we have reached the same conclusions, that is, that the applications of Bayonne, Community, JFK, Overlook, Raritan Bay, RWJ-Hamilton, Somerset, Trinitas and Virtua-Marlton should be approved. The same can be said about my approach and that of the SHPB, as we have reached the same conclusions regarding the need to approve the nine applicants recommended by staff as well as the applications submitted by Clara Maass, Holy Name, and Riverview.

FINDINGS AND DECISIONS ON INDIVIDUAL APPLICATIONS

Public input into the review process was achieved by permitting public comment on the demonstration project applications at the SHPB meeting that was held on July 10, 2008. SHPB members were provided with complete CN applications, completeness questions and answers, written comments from affected parties and Department staff recommendations in advance of their deliberations on these applications.

The SHPB, in accordance with N.J.S.A. 26:2H-5.8(b) and 26:2H-5.9(b), reviewed the applications at their July 10, 2008 public meeting and recommended approval of twelve applications. The Bayonne, Community, JFK, Overlook, Raritan Bay, RWJ-Hamilton, Somerset, Trinitas and Virtua-Marlton CN applications were recommended for approval with conditions by the SHPB by a unanimous 5 to 0 vote. These nine applicants were also recommended for approval by Department staff. The Riverview CN application was recommended for approval with conditions by the SHPB by a unanimous 5 to 0 vote. The Holy Name CN application was recommended for approval with conditions by the SHPB by a vote of 4 to 1. The Clara Maass CN application was recommended for approval with conditions by the SHPB by a vote of 3 to 2. In each case, the conditions recommended by the SHPB were identical to those recommended by Department staff. One additional condition was also placed on those applications from existing Atlantic C-PORT-E participant hospitals recommended for approval by the SHPB which would require compliance with the minimum annual PCI volume requirement for the second year of operation; failure to meet those volume requirements would result in the revocation of their elective angioplasty licenses. The volume of cases is of importance in terms of both a surrogate quality measure and in the interest of timely study completion and I find the elective angioplasty demonstration project rules (N.J.A.C. 8:33-3.11(e)) and the Department's rigorous cardiac service licensure process (N.J.A.C. 8:33E-1.13) provide sufficient authority for the Department to monitor

compliance. Therefore I am not requiring immediate revocation in the event an existing Atlantic C-PORT-E participant fails to meet the volume requirements; however, I will require the Department, through its licensing authority, to closely monitor each facility's volume.

Below are the findings and decision on individual applications, the Department's requirements with respect to the licensure process to be followed by successful demonstration project applicants, which are consistent with the SHPB recommendations, and the Department's monitoring of performance are briefly described. The conditions placed on each successful applicant also indicate the process that must be followed for initial licensure.

With regard to a determination of need under N.J.S.A. 26:2H-8, as I indicated earlier, the Department issued a call for a maximum of twelve elective angioplasty demonstration projects in accordance with N.J.A.C. 8:33-3.11(e).

As far as the current availability of elective angioplasty services is concerned, there are presently 18 cardiac surgery sites licensed and operating in New Jersey in addition to the nine elective angioplasty demonstration project hospitals that are being re-examined in this certificate of need process.

Since all of the eligible demonstration project hospital applicants already provide diagnostic cardiac catheterization and primary or emergency angioplasty services, there is no need for special equipment and services in the area. The same is true with respect to the availability of sufficient manpower in the several professional disciplines, since the necessary professionals are already providing angioplasty or PCI services on an emergency basis.

With respect to the adequacy of financial resources and sources of present and future revenues, Department staff reviewed and found that all applicants have documented adequate financial resources to implement and maintain the elective angioplasty demonstration project.

1 Bayonne Medical Center 071226-09-01 Hudson County

Hudson County is very densely populated and has a very high percentage of minority and medically underserved residents. Jersey City Medical Center, a cardiac surgery center located in Jersey City, and Bayonne Medical Center (Bayonne), as a current C-PORT-E demonstration project hospital participant, are currently providing elective angioplasty services in the County. In the interest of increasing access to care, I find that it is appropriate, for the duration of this demonstration project, to approve Bayonne to continue to participate in the Atlantic C-PORT-E Study as a second provider of elective angioplasty to serve this county. In 2006, 38.8 percent of Bayonne

diagnostic catheterization patients were minorities, demonstrating that this applicant has a strong track record in enhancing access to care.

Bayonne has successfully implemented an elective angioplasty demonstration project and has contributed valuable performance data as part of a scientifically rigorous multi-state demonstration project to determine the safety of the performance of elective angioplasty procedures without backup cardiac surgery on site. Bayonne has enrolled 107 elective PCI patients in CY 2006 and 124 elective PCI patients in CY 2007.

I find that with the exception of N.J.A.C. 8:33-3.11(e)6v, Bayonne has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Bayonne is one of five applicants located in the Newark/Jersey City hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas and Bayonne is one of only two applicants in this area (the other being Trinitas Hospital in Elizabeth) that are current Atlantic C-PORT-E demonstration project participants.

Bayonne has been a licensed primary PCI service provider since January 17, 2006 and an elective angioplasty demonstration project hospital since March 31, 2006.

Bayonne has satisfied all other pertinent criteria.

For the above reasons, I am approving Bayonne's application, with conditions. The conditions shall be as follows:

1. Bayonne's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Bayonne will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's

performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, Bayonne will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. Bayonne shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Bayonne drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Bayonne shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Bayonne's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Bayonne an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E provides notice that it is ceasing to enroll new patients, Bayonne shall cease performing elective angioplasty. Bayonne's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Bayonne an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State’s demonstration project will be terminated as well, and all demonstration sites, including Bayonne, shall immediately cease performing elective angioplasty. Bayonne's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Bayonne an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

2 Capital Health System – Mercer 071211-11-01 Mercer County

There is an alternative elective angioplasty provider located within Mercer County and Trenton City, that is St. Francis Medical Center, and several alternative providers located in contiguous counties (Middlesex and Burlington counties), thereby limiting the applicant’s ability to provide improved geographic access to this service to a greater extent than other competing applicants.

Access to medically underserved and minority populations in Mercer County is less likely to be expected to be greatly improved by this applicant, since the applicant’s service area is largely duplicative of that of the existing elective angioplasty provider located in Trenton City.

Capital Health System – Mercer (Capital-Mercer) has been granted CN approval to relocate the hospital, including the catheterization lab, to a new location in suburban Hopewell Township, outside the City of Trenton. This eventual relocation creates a degree of uncertainty about how well positioned this applicant would be in the future to enhance minority and medically underserved access to elective angioplasty.

Capital-Mercer's projected annual angioplasty volume to achieve compliance based on its historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. Capital-Mercer's projected annual volume of PCI cases places it nineteenth among the 22 applicants, making it less competitive in this regard. I find that approval of Capital-Mercer's demonstration application would therefore not contribute to the timely completion of the research study.

Capital-Mercer is one of two demonstration project applicants located in the Trenton hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services. Capital-Mercer ranks first among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas; however, as discussed above, because Capital-Mercer's service area is largely duplicative of that of the existing elective angioplasty provider located in Trenton City, its ability to increase access to minority and medically underserved populations is not expected to be significant. In addition, Capital Mercer ranks second in terms of projected PCI volume. I find that approval of Capital-Mercer would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying the application of Capital-Mercer.

3 Chilton Memorial Hospital 071225-14-01 Morris County

There is an alternative elective angioplasty provider located in Morris County (i.e., Morristown Memorial Hospital) as well as numerous elective angioplasty providers in counties contiguous to Morris County (Essex and Passaic counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing applicants that are able to document enhanced access to medically underserved population groups in other regions in the State.

Chilton Memorial Hospital's (Chilton) projected annual angioplasty volume, based on its historical catheterization laboratory, places it 13 among the 22 applicants making it less competitive in this regard. I find that approval of Chilton's demonstration application would therefore not contribute to the timely completion of the demonstration project.

Chilton is located in the Hackensack, Ridgewood, Paterson hospital market area, which is one of eight relevant geographic area defined by the New Jersey Commission on Rationalizing Health Care Resources. Within this hospital market area there are five alternative cardiac surgery centers providing elective angioplasty services. Chilton Memorial Hospital ranks second among the two demonstration project applicants located in this region with respect to providing access to minority and medically underserved populations in their respective service areas. I find that approval of Chilton would not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying the application of Chilton.

4 Christ Hospital 071223-09-01 Hudson County

There is an alternative elective angioplasty provider located in relatively close proximity to the applicant in Jersey City, Hudson County and numerous alternative elective angioplasty providers located in counties contiguous to Hudson County (Essex and Bergen counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing applicants that are able to document enhanced access to population groups in other regions in the State.

Christ Hospital's projected annual angioplasty volume to achieve compliance based on its historical catheterization laboratory, places it 20 among the 22 applicants, making it less competitive in this regard than other competing demonstration applicants. I find that approval of Christ Hospital's demonstration application would therefore not contribute to the timely completion of the demonstration project.

Access to medically underserved and minority populations in Hudson County is not expected to be greatly improved by this applicant, since the applicant's service areas is, for the most part, duplicative of an existing elective angioplasty provider that is located in Jersey City.

Christ Hospital is one of five applicants located in the Newark/Jersey City hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area, there are five alternative cardiac surgery centers providing elective angioplasty.

For the above reasons, I am denying the application of Christ Hospital.

5 Clara Maass Medical Center 071217-07-01 Essex County

Clara Maass Medical Center (Clara Maass) provided services to a high percentage of minority diagnostic catheterization patients in 2006, 45.3 percent, thereby documenting that access by minority and medically underserved populations is likely to be improved to a greater extent by Clara Maass than by other competing applicants. Clara Maass has been able to document the ability to provide its current cardiac services to these population groups.

Projected annual angioplasty volume to achieve compliance with Atlantic C-PORT-E study minimum volume criteria or minimum State annual volume criteria, as set forth at N.J.A.C. 8:33E-2.3(d)1, based on Clara Maass' historical catheterization laboratory performance, would be more likely to occur in comparison to other competing demonstration applicants. I also agree with the SHPB's reasoning in recommending approval of Clara Maass, which emphasized the fact that recent area hospital closures may serve to enhance Clara Maass' market share and thereby achieve compliance with State regulatory and Atlantic C-PORT-E Study volume requirements. I find that approval of Clara Maass would therefore contribute to the timely completion of the demonstration project.

Clara Maass is one of five applicants located in the Newark/Jersey City hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area, Clara Maass ranks third among the five applicants with respect to providing access to minority and medically underserved populations in their respective service areas and second in terms of projected PCI volume. I find that approval of Clara Maass would therefore contribute to improved access and the timely completion of the demonstration project in comparison with other competing applicants.

In its presentation before the SHPB, Clara Maass noted that it is a member of Saint Barnabas Health System, which includes both Newark Beth Israel Medical Center and Saint Barnabas Medical Center, two of the existing providers of elective angioplasty in Essex County. As such, most of Clara Maass' interventional cardiologists are on the staff of one or both of these hospitals and the common medical staff will permit randomized patients, in many cases, to be treated by the same cardiologists. I find that this will effectively limit variability and support the integrity of the Study.

Clara Maass has been a licensed primary PCI service provider since June 3, 2005.

For the above reasons, I am approving the application of Clara Maass with conditions. The conditions shall be as follows:

1. Clara Maass shall document final approval from its Institutional Review Board and acceptance for participation in the Atlantic C-PORT-E Study prior to being licensed for the elective angioplasty service by the Department.
2. Clara Maass shall be licensed by the Department as a demonstration project elective angioplasty provider no later than six months from CN approval. This

certificate of need approval shall expire on that date, regardless of whether or not Clara Maass has been licensed.

3. Clara Maass' license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Clara Maass will be issued a separate demonstration project license and be evaluated at any time at the discretion of the Department and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As a new elective angioplasty demonstration project provider, Clara Maass will be required to fully meet the facility PCI volume requirement, set forth at N.J.A.C. 8:33-3.11(e)6v., for the first, second and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date approval to enroll patients in the Atlantic C-PORT-E Study.
4. Upon review of its licensure as a Demonstration Project Hospital, Clara Maass shall be subject to reporting to the Department, renewal, and/or plan of correction or termination of participation.
5. Clara Maass shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
6. Should Clara Maass drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Clara Maass shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Clara Maass' license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Clara Maass an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
7. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Clara Maass shall cease performing elective angioplasty. Clara Maass' license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Clara Maass an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
8. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Clara Maass, shall immediately cease performing elective angioplasty. Clara Maass' license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Clara Maass an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

6 Community Medical Center 071220-15-01 Ocean County

Community Medical Center ("Community") has provided the largest volume of diagnostic cardiac catheterization cases of all of the demonstration project applicants during each of the past two calendar years (18 percent higher than the second highest volume demonstration applicant), thereby providing high projected demonstration project elective angioplasty case volume indicating that it can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1 and contribute toward a timely completion of the demonstration project.

Community is located in Ocean County where there is no elective angioplasty provider currently licensed.

Community has the highest projected demonstration project annual case volume, with 379 cases. Although the proportion of minorities among Community's 2006 diagnostic catheterization patients was only 4.5 percent, ranking Community twentieth out of the 22 applicants, a review of the demographic characteristics of Community's service area demonstrates that the over 45 population is comprised of only 2.8 percent non-white. Therefore, I find that Community's provision of cardiac catheterization to minority patients to be comparable to the percentage of non-white residents in the service area.

With respect to the impact of a Community approval on existing providers, I also note that 10.6 percent of Deborah Heart and Lung Center's (Deborah) angioplasty cases in 2006 came from Community's service area and that the likelihood that each of these patients would choose to be enrolled in the Atlantic C-PORT-E Study is questionable. In addition to this potential impact, an additional 33 PCI cases (representing 2.2 percent of Deborah's 2006 PCI volume) came from the Virtua-Marlton service area. I am aware of the fact that former Commissioner Jacobs denied Community's prior application to participate in the elective angioplasty project because of the potential impact on Deborah. I am persuaded that an award of a CN to Community will have no greater impact on Deborah than the many other factors related to a competitive and changing healthcare market, especially in light of the growing senior demographic in Ocean County, the overall volume and percentage of the cases enrolled in the demonstration project, and the anticipated completion of the project by approximately 2010. I agree with both the staff and the SHPB that Ocean County's lack of an existing elective angioplasty provider, together with the fact that Community's percentage of minority patients is representative of minority presence in the service area, outweighs the potential negative impact on existing providers. The magnitude of the potential impact on Deborah has greatly diminished since the previous demonstration project review process in 2005, when the combined potential impact of a Community and Virtua-Marlton approval was projected to be a maximum of 48 percent rather than the 12.8 percent in this current review process.

Furthermore, I find that Community has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic

C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Participating Community interventional cardiologists, with a single exception, meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration project.

Community has been a licensed primary PCI service provider since June 6, 2005.

Community is one of four demonstration project applicants located in the Toms

For the above reasons, I am approving Community's application with conditions. The conditions shall be as follows:
River hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and Community ranks first in terms of projected PCI volume among the other demonstration project applicants in the market area. I find that approval of Community would therefore contribute to the timely completion of the demonstration project in comparison with other competing applicants.

1. Community shall document final approval from its Institutional Review Board and acceptance for participation in the Atlantic C-PORT-E Study prior to being licensed for the elective angioplasty service by the Department.
2. Community shall be licensed by the Department as a demonstration project elective angioplasty provider no later than six months from CN approval. This certificate of need approval shall expire on that date, regardless of whether or not Community has been licensed.
3. Community's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Community will be issued a separate demonstration project

license and be evaluated at any time at the discretion of the Department and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As a new elective angioplasty demonstration project provider, Community will be required to fully meet the facility PCI volume requirement, set forth at N.J.A.C. 8:33-3.11(e)6v., for the first, second and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date approval to enroll patients in the Atlantic C-PORT-E Study.

4. Upon review of its licensure as a Demonstration Project Hospital, Community shall be subject to reporting to the Department, renewal, and/or plan of correction or termination of participation.
5. Community shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
6. Should Community drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Community shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Community's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Community an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
7. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Community shall cease performing elective angioplasty. Community's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Community an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
8. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Community, shall immediately cease performing elective angioplasty. Community's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Community an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

7 Holy Name Hospital 071213-02-01 Bergen County

Holy Name Hospital (Holy Name) is located in the populous Northeast portion of New Jersey. Because I believe that the staff recommendations did not provide sufficient representation in this demonstration project to applicants from the

Northeastern region of the State, I agree with the SHPB that approval of Holy Name's application will improve geographic access to elective angioplasty.

Furthermore, Holy Name has a significant commitment to research, particularly for a community hospital. The SHPB found persuasive Holy Name's affirmation that the hospital has restructured its cardiac catheterization program by adding four minority interventional cardiologists and would meet volume requirements. In addition, Holy Name's acquisition of a Korean medical department, including 50 physicians and two interventional cardiologists, will result in additional volume and improved access. I find that Holy Name's ability to contract with Hackensack University Medical Center as the primary partner in the Atlantic C-PORT-E Study, as well as the other two cardiac surgery centers in Bergen County, will serve to minimize the impact on the existing alternative providers. As a consequence, I find Holy Name has demonstrated that its elective angioplasty demonstration project program would continue to be of high quality.

Holy Name is one of two demonstration project applicants that are located in the Hackensack, Ridgewood, Paterson hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area Holy Name ranks first of the two applicants with respect to the provision of services to minority and medically underserved populations and eighth among the 22 applicants in this category.

Holy Name has been a licensed primary PCI service provider since October 26, 2005.

I find that Holy Name has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

I agree with the SHPB's recommendation that Holy Name will achieve the target 200 cases per year during the demonstration project.

Holy Name has satisfied all other pertinent criteria.

For the above reasons, I am approving Holy Name's application, with conditions. The conditions shall be as follows:

1. Holy Name's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Holy Name will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, Holy Name will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.
2. Holy Name shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Holy Name drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Holy Name shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Holy Name's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Holy Name an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Holy Name shall cease performing elective angioplasty. Holy Name's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Holy Name an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Holy Name, shall immediately cease performing elective angioplasty. Holy Name's license shall be returned to the Department within 30 days of the date that enrollment ceases, and the Department shall issue Holy Name an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

Actual annual elective and primary angioplasty volume for Monmouth Medical Center (Monmouth), which amounted to only 86 total PCI cases in 2007, is indicative of Monmouth's inability to achieve compliance with Atlantic C-PORT-E minimum volume criterion or minimum State facility volume criteria, as set forth at N.J.A.C. 8:33E-2.3(e) and N.J.A.C. 8:33-3.11(e)6v., and therefore I find that continuation of Monmouth as an elective angioplasty demonstration project would not contribute to the timely completion of the demonstration project in comparison to other competing applicants.

There is an alternative elective angioplasty provider located in Monmouth County and several elective angioplasty providers located in counties contiguous to Monmouth County (Middlesex, Mercer and Burlington counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing applicants.

Monmouth is one of four demonstration project applicants located in the Toms River hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and although Monmouth ranks first among the four applicants with respect to providing access to minority and medically underserved populations in their respective service areas, it ranks fourth in terms of projected PCI volume. I find that approval of Monmouth as an elective angioplasty demonstration project would not contribute to the timely completion of the demonstration project in comparison to other competing applicants.

For the above reasons, I am denying Monmouth's application.

In accordance with condition number five placed on Monmouth's October 31, 2005 certificate of need approval as an elective angioplasty demonstration project, Monmouth shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Atlantic C-PORT-E Study. Monmouth's license shall be returned to the Department within thirty days of the date that enrollment ceases and the Department shall issue Monmouth an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

9 JFK Medical Center 071215-12-01 Middlesex County

JFK Medical Center (JFK) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume

specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Participating JFK interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional PCI volume standard at N.J.A.C. 8:33E-2.16(b)6. These interventional cardiologists also agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria and agree to obtain necessary informed consent for patient participation in the demonstration project.

JFK has been a licensed primary PCI service provider since September 21, 2006.

JFK has provided the eighth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing projected demonstration project elective angioplasty case volume that is capable of achieving the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1.

JFK is in compliance with licensing requirements for the cardiac services that are already being provided at the hospital.

Access to medically underserved and minority populations in Middlesex and Union Counties can be expected to be greatly improved by the selection of JFK as a demonstration site, since the applicant's primary and secondary service areas contain significant minority and medically underserved populations that have been historically served by the applicant.

JFK is one of six demonstration project applicants located in the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services. JFK ranks third among the six applicants with respect to providing access to minority and medically underserved populations in their respective service areas and fourth in terms of projected PCI volume. Given JFK's comparatively sizeable projected PCI volume and minority service provision, I find that approval of JFK would contribute to both improved access and the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am approving JFK's application with conditions.

The conditions shall be as follows:

1. JFK shall obtain approval from its Institutional Review Board and approval for participation in the Atlantic C-PORT-E Study prior to being licensed for the elective angioplasty service by the Department.
2. JFK shall be licensed by the Department as a demonstration project elective angioplasty provider no later than six months from CN approval. This certificate of need approval shall expire on that date, regardless of whether or not JFK has been licensed.
3. JFK's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. JFK will be issued a separate demonstration project license and be evaluated at any time at the discretion of the Department and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As a new elective angioplasty demonstration project provider, JFK will be required to fully meet the facility PCI volume requirement, set forth at N.J.A.C. 8:33-3.11(e)6v., for the first, second and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date approval to enroll patients in the Atlantic C-PORT-E Study.
4. Upon review of its licensure as a Demonstration Project Hospital, JFK shall be subject to reporting to the Department, renewal, and/or plan of correction or termination of participation.
5. JFK shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
6. Should JFK drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, JFK shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. JFK's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue JFK an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
7. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, JFK shall cease performing elective angioplasty. JFK's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue JFK an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
8. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including JFK, shall immediately

cease performing elective angioplasty. JFK's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue JFK an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

10 Ocean Medical Center 071231-15-01 Ocean County

Ocean Medical Center – Brick is the second ranked demonstration applicant located in Ocean County (fourth ranked overall) in terms of potential angioplasty cases, with calendar years 2005-2007 diagnostic catheterizations and projected angioplasty based on this utilization below that of the competing applicant located in the County.

The applicant's projected demonstration project elective angioplasty case volume is not significantly greater than other competing applicants that have been able to document their ability to enhance access to this service to medically underserved and minority populations residing within their respective service areas.

Ocean Medical Center – Brick is one of four demonstration project applicants located in the Toms River hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services, and Ocean ranks third among the four applicants with respect to providing access to minority and medically underserved populations in their respective service areas and second in terms of projected PCI volume. I find that approval of Ocean Medical Center - Brick would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying Ocean's application.

11 Overlook Hospital 071212-20-01 Union County

I find that Overlook Hospital (Overlook) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C.

8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

For the most part, participating Overlook's interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration project.

Overlook has been a licensed primary PCI service provider since May 1, 2003.

Overlook has provided the tenth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing projected demonstration project angioplasty case volume that can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1.

Overlook is located in Union County, where there is currently no elective angioplasty provider other than Trinitas Hospital located in Elizabeth and thereby its approval would continue to improve geographic access to this service.

Overlook is in compliance with licensing requirements for the cardiac services that are already being provided at the hospital.

Access to medically underserved and minority populations in Union County can be expected to continue to be improved by the selection of Overlook as a demonstration site, since the applicant's primary and secondary service areas contain significant minority and medically underserved populations that have been largely served by the applicant. Overlook's operation of a satellite emergency department (SED) at the former Union Hospital location also serves to demonstrate its commitment to the provision of services to these population groups.

Overlook Hospital is one of two applicants located in the Morristown hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services, and Overlook Hospital ranks first among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas and also in terms of projected PCI volume. I find that approval of Overlook would therefore contribute to improved access and timely completion of the demonstration project in comparison with other competing applicants.

In its presentation before the SHPB, Overlook noted that it is a member of Atlantic Health System, which includes Morristown Memorial Hospital, the only existing provider of elective angioplasty in Morris County. As such, all of Overlook's interventional cardiologists are on the staff of Morristown Memorial Hospital and the common medical staff will permit randomized patients to be treated by the same cardiologists. I find that this will effectively limit variability and support the integrity of the Study.

For the above reasons, I am approving Overlook's application with conditions. The conditions shall be as follows:

1. Overlook shall document final approval from its Institutional Review Board and acceptance for participation in the Atlantic C-PORT-E Study prior to being licensed for the elective angioplasty service by the Department.
2. Overlook shall be licensed by the Department as a demonstration project elective angioplasty provider no later than six months from CN approval. This certificate of need approval shall expire on that date, regardless of whether or not Overlook has been licensed.
3. Overlook's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Overlook will be issued a separate demonstration project license and be evaluated at any time at the discretion of the Department and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As a new elective angioplasty demonstration project provider, Overlook will be required to fully meet the facility PCI volume requirement, set forth at N.J.A.C. 8:33-3.11(e)6v., for the first, second and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date approval to enroll patients in the Atlantic C-PORT-E Study.
4. Upon review of its licensure as a Demonstration Project Hospital, Overlook shall be subject to reporting to the Department, renewal, and/or plan of correction or termination of participation.
5. Overlook shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
6. Should Overlook drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Overlook shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Overlook's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Overlook an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

7. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Overlook shall cease performing elective angioplasty. Overlook's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Overlook an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
8. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Overlook, shall immediately cease performing elective angioplasty. Overlook's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Overlook an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

12 Raritan Bay Medical Center 071207-12-01 Middlesex County

I find that Raritan Bay Medical Center(Raritan Bay) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Participating Raritan Bay interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration project.

Raritan Bay has been a licensed primary PCI service provider since April 6, 2004.

Raritan Bay has provided the second largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing high projected demonstration project elective angioplasty case volume that can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1 and N.J.A.C. 8:33-3.11(e)6v., and contribute toward a timely completion of the demonstration project.

Raritan Bay is in compliance with licensing requirements for the cardiac services that are already being provided at the hospital.

Access to medically underserved and minority populations can be expected to be improved in Middlesex and western Monmouth counties, since the applicant's service area contains significant minority and medically underserved populations that have been historically served by the applicant.

Raritan Bay is one of six demonstration project applicants located within the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services, and Raritan Bay ranks second among the six applicants with respect to providing access to minority and medically underserved populations in their respective service areas and in terms of projected PCI volume. I find that approval of Raritan Bay would therefore contribute to improved access and the timely completion of the demonstration project in comparison with other competing applicants.

Raritan Bay has satisfied all other pertinent criteria.

For the above reasons, I am approving Raritan Bay's application, with conditions. The conditions shall be as follows:

1. Raritan Bay's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Raritan Bay will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, Raritan Bay will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. Raritan Bay shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Raritan Bay drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Raritan Bay shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Raritan Bay's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Raritan Bay an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Raritan Bay shall cease performing elective angioplasty. Raritan Bay's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Raritan Bay an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Raritan Bay, shall immediately cease performing elective angioplasty. Raritan Bay's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Raritan Bay an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

13 Riverview Medical Center 071221-13-01 Monmouth County

Riverview Medical Center (Riverview) has provided the sixteenth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing projected demonstration project elective angioplasty case volume that would be sufficient to achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1 and N.J.A.C. 8:33-3.11(e)6v., and would therefore contribute toward a timely completion of the demonstration project in comparison to other competing applicants.

Riverview has been a licensed primary PCI service provider since July 27, 2004.

Riverview is one of four demonstration project applicants located in the Toms River hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and Riverview ranks second among the four applicants with respect to providing access to minority and medically underserved populations in their respective service areas and third in terms of projected PCI volume. I find that approval of Riverview would therefore contribute to improved access to residents of northern

Monmouth County and the timely completion of the demonstration project in comparison with other competing applicants.

In its presentation before the SHPB, Riverview emphasized that it is a member of Meridian Health System, which includes Jersey Shore Medical Center, the only existing provider of elective angioplasty in Monmouth County. As such, all of Riverview's interventional cardiologists are on the staff of Jersey Shore Medical Center and the common medical staff will permit randomized patients to be treated by the same cardiologists. I find that this will effectively limit variability and support the integrity of the Study.

For the above reasons, I am approving Riverview's application with conditions. The conditions shall be as follows:

1. Riverview shall document final approval from its Institutional Review Board and acceptance for participation in the Atlantic C-PORT-E Study prior to being licensed for the elective angioplasty service by the Department.
2. Riverview shall be licensed by the Department as a demonstration project elective angioplasty provider no later than six months from CN approval. This certificate of need approval shall expire on that date, regardless of whether or not Riverview has been licensed.
3. Riverview's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Riverview will be issued a separate demonstration project license and be evaluated at any time at the discretion of the Department and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As a new elective angioplasty demonstration project provider, Riverview will be required to fully meet the facility PCI volume requirement, set forth at N.J.A.C. 8:33-3.11(e)6v., for the first, second and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date approval to enroll patients in the Atlantic C-PORT-E Study.
4. Upon review of its licensure as a Demonstration Project Hospital, Riverview shall be subject to reporting to the Department, renewal, and/or plan of correction or termination of participation.
5. Riverview shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
6. Should Riverview drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Riverview shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Riverview's license shall be returned to the Department within thirty

days of the date that its participation ceases, and the Department shall issue Riverview an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

7. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Riverview shall cease performing elective angioplasty. Riverview's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Riverview an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
8. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Riverview, shall immediately cease performing elective angioplasty. Riverview's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Riverview an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

14 Robert Wood Johnson Med. Center at Hamilton 071227-11-01 Mercer County

I find that Robert Wood Johnson Medical Center at Hamilton (RWJ/Hamilton) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Participating RWJ/Hamilton interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined

device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration project.

RWJ/Hamilton has been a licensed primary PCI service provider since March 19, 2003.

RWJ/Hamilton has provided the fifth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing projected demonstration project angioplasty case volume that can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1 and N.J.A.C. 8:33-3.11(e)6v.

RWJ/Hamilton has successfully implemented an elective angioplasty demonstration project and has contributed valuable performance data as part of a scientifically rigorous multi-state study to determine the safety of the performance of elective angioplasty procedures without backup cardiac surgery on site. (RWJ/Hamilton has enrolled 36 elective PCI patients in CY 2006 and 80 elective PCI patients in CY 2007).

I find that access to medically underserved and minority populations in Mercer County is more likely to be greatly improved by this applicant, since 25 percent of RWJ/Hamilton's elective PCI enrollees in 2007 were minorities.

RWJ/Hamilton is one of two demonstration project applicants located in the Trenton hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services, and although RWJ/Hamilton ranks second among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas, it ranks first in terms of projected PCI volume. I find that approval of RWJ/Hamilton would therefore contribute to both improved access and the timely completion of the demonstration project in comparison with other competing applicants.

RWJ/Hamilton has satisfied all other pertinent criteria.

For the above reasons, I am approving RWJ/Hamilton's application, with conditions. The conditions shall be as follows:

1. RWJ/Hamilton's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. RWJ/Hamilton will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum

facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, RWJ/Hamilton will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. RWJ/Hamilton shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should RWJ/Hamilton drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, RWJ/Hamilton shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. RWJ/Hamilton's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue RWJ/Hamilton an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, RWJ/Hamilton shall cease performing elective angioplasty. RWJ/Hamilton's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue RWJ/Hamilton an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including RWJ/Hamilton, shall immediately cease performing elective angioplasty. RWJ/Hamilton's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue RWJ/Hamilton an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

15 Somerset Medical Center 71222-18-01 Somerset County

I find that Somerset Medical Center (Somerset) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties

performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

Participating Somerset interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to continue to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to continue to obtain necessary informed consent for patient participation in the demonstration project.

Somerset has been a licensed primary PCI service provider since June 16, 2003.

Somerset has provided the third largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during each of the past three calendar years (2005-2007), thereby providing high projected demonstration project elective angioplasty case volume that can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1 and contribute toward a timely completion of the Study.

Somerset is the only general hospital in Somerset County and therefore there is no alternative elective angioplasty provider.

Somerset is in compliance with licensing requirements for the cardiac services that are already being provided at the hospital.

Somerset is one of six demonstration project applicants located in the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and Somerset ranks first in terms of projected PCI volume. I find that approval of Somerset would therefore contribute to the timely completion of the demonstration project in comparison with other competing applicants.

Somerset has satisfied all other pertinent criteria.

For the above reasons, I am approving Somerset's application, with conditions. The conditions shall be as follows:

1. Somerset's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Somerset will be issued a separate demonstration project

license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, Somerset will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. Somerset shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Somerset drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Somerset shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Somerset's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Somerset an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Somerset shall cease performing elective angioplasty. Somerset's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Somerset an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Somerset, shall immediately cease performing elective angioplasty. Somerset's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Somerset an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

16 St. Clare's Medical Center – Denville 071210-14-01 Morris County

I find that there is an alternative elective angioplasty provider located in Morris County (i.e., Morristown Memorial Hospital) as well as numerous alternative elective angioplasty providers in counties contiguous to Morris County (Essex and Passaic counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing demonstration applicants that are able to document enhanced access to medically underserved population groups in other regions in the State.

Projected annual angioplasty volume to achieve compliance with Atlantic C-PORT-E study minimum volume criteria or minimum State annual volume criteria, as set forth at N.J.A.C. 8:33E-2.3(d)1 and N.J.A.C. 8:33-3.11(e)6v, based on St. Clare's Hospital historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. I find that approval of St. Clare's Hospital's demonstration application would therefore not contribute to the timely completion of the Study.

St. Clare's Hospital is one of two applicants located in the Morristown hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services, and St. Clare's Hospital ranks second among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas and also in terms of projected PCI volume. I find that approval of St. Clare's would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying St. Clare's application.

17 Mountainside Hospital 071228-07-01 Essex County

Projected annual angioplasty volume to achieve compliance with Atlantic C-PORT-E study minimum volume criteria or minimum State annual volume criteria, as set forth at N.J.A.C. 8:33E-2.3(d)1, based on Mountainside Hospital's (Mountainside) historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. I find that approval of Mountainside would therefore not contribute to the timely completion of the demonstration project.

The applicant's projected demonstration project elective angioplasty case volume, the twenty-first largest projected annual volume among the 22 applicants, is not significantly greater than other competing applicants that have been able to document their ability to enhance access to this service by medically underserved and minority populations residing within their service areas. I find that approval of Mountainside would therefore not contribute to the timely completion of the Study.

I find that Mountainside would not improve access to minority and medically underserved populations in its service area to a greater extent than other competing demonstration applicants that are located within service areas, including those located within Essex County or include Essex County in their primary service area, with higher levels of minority and medically underserved populations and have documented the ability to provide its current cardiac services to these population groups.

Mountainside is one of five applicants located in the Newark/Jersey City hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area, there are five alternative cardiac surgery centers providing elective angioplasty services and Mountainside ranks fifth among the five applicants with respect to providing access to minority and medically underserved populations in their respective service areas and also in terms of projected PCI volume. I find that approval of Mountainside would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying Mountainside's application.

18 Trinitas Hospital – Williamson Street 071209-20-01 UNION COUNTY

I find that Trinitas Hospital (Trinitas) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

For the most part, participating Trinitas interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration project.

Trinitas has been a licensed primary PCI service provider since October 15, 2003.

Trinitas has provided the ninth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants (including two other demonstration applicants located in Union County) during the past three calendar years (2005-2007), thereby providing projected demonstration project angioplasty case

volume that can achieve the required minimum facility volume standard (200 cases/year) as set forth at N.J.A.C. 8:33E-2.3(d)1.

Trinitas is located in Union County and its approval would continue to improve geographic access to this service.

Trinitas is in compliance with licensing requirements for the cardiac services that are already being provided at the hospital.

Access to medically underserved and minority populations in Union County can be expected to continue to be greatly improved by the selection of Trinitas as a demonstration site, since the applicant's primary and secondary service areas contain significant minority and medically underserved populations that have been historically served by the applicant.

Trinitas is one of five applicants located in the Newark/Jersey City hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area, however, there are five alternative cardiac surgery centers providing elective angioplasty services and Trinitas Hospital ranks first among the five applicants with respect to both providing access to minority and medically underserved populations in their respective service areas and projected PCI volume. Approval of Trinitas would therefore contribute to both improved access and the timely completion of the demonstration project in comparison with other competing applicants.

Trinitas has satisfied all other pertinent review criteria.

For the above reasons, I am approving Trinitas' application, with conditions. The conditions shall be as follows:

1. Trinitas' license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Trinitas will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the Department. As an existing elective angioplasty demonstration project provider, Trinitas will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. Trinitas shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Trinitas drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Trinitas shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Trinitas' license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Trinitas an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Trinitas shall cease performing elective angioplasty. Trinitas' license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Trinitas an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State's demonstration project will be terminated as well, and all demonstration sites, including Trinitas, shall immediately cease performing elective angioplasty. Trinitas' license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Trinitas an amended license deleting its authorization to participate in the elective angioplasty demonstration project.

19 Virtua-West Jersey Hospital - Marlton 071230-03-01 Burlington County

I find that Virtua-West Jersey Hospital-Marlton (Virtua-Marlton) has sufficiently documented the ability to satisfy demonstration project eligibility criteria at N.J.A.C. 8:33-3.11(e)4 and the Atlantic C-PORT-E Study site inclusion criteria, including: (a) how the applicant will satisfy the patient selection criteria specified in the Atlantic C-PORT-E protocol, which is designed to assure informed consent and appropriate randomization, as provided in the Manual of Operations (N.J.A.C. 8:33-3.11(e)6iii); (b) approval of the study protocol by the applicant's Institutional Review Board, and if approval is pending, the status of that application (N.J.A.C. 8:33-3.11(e)6iv); (c) how the applicant will meet the target volume specified in the Atlantic C-PORT-E protocol of primary and elective angioplasties performed at the applicant's site, after randomization (that is, 100 PCI cases in year one and 200 cases in year two and each year thereafter) (N.J.A.C. 8:33-3.11(e)6v); (d) the applicant's compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16, 2.16(b) and N.J.A.C. 8:43G-7 (N.J.A.C. 8:33-3.11(e)6vi); and (e) documentation of the applicant's willingness to report elective PCI data to the Department separate from data collected as part of the study protocol, to support the Department's ongoing monitoring of cardiac services pursuant to N.J.A.C. 8:33E-1.9 and 2.10 (N.J.A.C. 8:33-3.11(e)6vii).

I find that participating Virtua-Marlton interventional cardiologists meet and are expected to continue to meet the annual Statewide interventional volume standard at N.J.A.C. 8:33E-2.16(b)6; agree to practice in accordance with the Atlantic C-PORT-E-defined device and patient selection criteria; and agree to obtain necessary informed consent for patient participation in the demonstration.

Virtua-Marlton has been a licensed primary PCI service provider since December 2, 2004.

Virtua-Marlton has provided the sixth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing projected demonstration project angioplasty case volume that will serve to contribute to the timely completion of the Study.

Virtua-Marlton is the only demonstration applicant that is located within the seven southernmost counties in New Jersey, which have fewer primary and elective angioplasty providers per capita than hospitals located in the Northern and Central New Jersey regions. There is only one licensed elective angioplasty provider in Burlington County (i.e., Deborah Heart and Lung Center), where Virtua-Marlton is located.

With respect to the impact of a Virtua-Marlton approval on existing providers, I also note that 2.2 percent of Deborah Heart and Lung Center's (Deborah) angioplasty cases in 2006 came from Virtua-Marlton service area. The likelihood that each of these patients would choose to be enrolled in Atlantic C-PORT-E is questionable. In addition to this potential impact, 10.6 percent of Deborah's 2006 PCI volume are derived by Deborah from the Community service area. I am persuaded that an award of a CN to Virtua-Marlton will have no greater impact on Deborah than the many other factors related to a competitive and changing healthcare market. The magnitude of the potential impact on Deborah has greatly diminished since the previous demonstration project review process in 2005, when the combined potential impact of a Community and Virtua-Marlton approval was projected to be a maximum of 48 percent rather than the 12.8 percent in this current review process.

As the Department's staff review indicated, Our Lady of Lourdes Medical Center (Lourdes) is Virtua-Marlton's primary referral center (258, or 94.5 percent of Marlton's combined PCI and cardiac surgery referrals in 2006). Our Lady of Lourdes angioplasty volume was 2,343 in 2006 and the impact of 75 percent of Marlton's referrals being lost would account for 194 cases or 8.3 percent of Our Lady of Lourdes' volume, assuming all the referrals were for angioplasty. Furthermore, total PCI facility volume at Lourdes consistently exceeds the statewide average volume of PCI cases at the State's 18 cardiac surgery centers (2343 vs. 1596 in 2006; 1762 vs. 1432 in 2007).

Current Department PCI data (July, 2007 – June, 2008) indicate that all six of Virtua-Marlton's interventionalists perform PCI cases at Lourdes and two of these interventionalists also perform PCI cases at AtlantiCare Regional Medical Center. On

the other hand, none of Virtua-Marlton's interventional cardiologists performed PCI cases at Cooper University Hospital (Cooper). Furthermore, the PCI data also indicate that the three interventional cardiologists performing the bulk (93.6 percent) of PCI cases at Virtua-Marlton continue to perform the vast majority of their PCI cases at Lourdes (26 percent at Virtua-Marlton; 73.9 percent at Lourdes). I am therefore equally persuaded that an award of a CN to Virtua-Marlton will have no greater impact on Lourdes than the many other factors related to a competitive and changing healthcare market. I have reviewed the potential impact related to volume and scope on urban areas and find that the participation by Virtua-Marlton in the demonstration project would not significantly impact access or volume in the Camden hospital market area.

Other than the applicant's inability to achieve the minimum annual primary PCI volume of 36 cases, having performed 35 in 2007, Virtua-Marlton is in compliance with all other licensing requirements for the cardiac services that are already being provided at the hospital.

Access to medically underserved and minority populations can be expected to improve with the selection of Virtua-Marlton since the applicant's service area does contain sizeable minority and medically underserved populations.

Virtua-Marlton is the only demonstration project applicant located in the Camden hospital market area which the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there are three alternative cardiac surgery centers providing elective angioplasty services and Virtua-Marlton's percentage of minority and medically underserved patients is comparable to the minority and medically underserved populations in its service area and ranks sixth of all applicants in terms of projected PCI volume. I find that approval of Virtua-Marlton would therefore contribute to both improved access and the timely completion of the demonstration project in comparison with other competing applicants.

Virtua-Marlton has satisfied all other pertinent criteria.

For the above reasons, I am approving Virtua-Marlton's application, with conditions. The conditions shall be as follows:

1. Virtua-Marlton's license to perform elective angioplasty shall not exceed three years, and shall be subject to annual licensure review for compliance with State licensure standards. Virtua-Marlton will be issued a separate demonstration project license and evaluated at any time period at the Department's discretion and at the end of the first and second years for full compliance with all elective angioplasty demonstration project requirements, including annual minimum facility and physician volume. In accordance with N.J.A.C. 8:33E-2.3(d)4, physician volume compliance will be calculated on the basis of the physician's performance of PCI in the most recent calendar year available to the

Department. As an existing elective angioplasty demonstration project provider, Virtua-Marlton will be required to fully meet the facility PCI volume requirement set forth at N.J.A.C. 8:33E-2.3(d)2 for the first and each subsequent year. In accordance with N.J.A.C. 8:33E-2.3(d)2, minimum facility volume compliance each year will be calculated on the basis of the last four quarters of PCI operation prior to the demonstration project licensure anniversary date.

2. Virtua-Marlton shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. Should Virtua-Marlton drop out of the Atlantic C-PORT-E Study, whether voluntarily or involuntarily, Virtua-Marlton shall immediately cease performing elective angioplasty and shall notify the Department of the termination of its participation in the Study. Virtua-Marlton's license shall be returned to the Department within thirty days of the date that its participation ceases, and the Department shall issue Virtua-Marlton an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
4. As soon as the Atlantic C-PORT-E Study provides notice that it is ceasing to enroll new patients, Virtua-Marlton shall cease performing elective angioplasty. Virtua-Marlton's license shall be returned to the Department within thirty days of the date that enrollment ceases, and the Department shall issue Virtua-Marlton an amended license deleting its authorization to participate in the elective angioplasty demonstration project.
5. Should all Atlantic C-PORT-E Study enrollment conclude abruptly as a result of application of the Study's stopping rules, because the early evidence convincingly indicates safety problems, the State’s demonstration project will be terminated as well, and all demonstration sites, including Virtua-Marlton, shall immediately cease

20 University Medical Center at Princeton 071208-11-01 Mercer County

There is an alternative elective angioplasty provider located within Mercer County (i.e., St. Francis Medical Center) and several alternative providers located in contiguous counties (Middlesex and Burlington counties), thereby limiting University Medical Center at Princeton’s (Princeton) ability to provide improved geographic access to this service to a greater extent than other competing applicants.

Princeton has been granted CN approval to relocate the hospital, including the catheterization lab, to a new location in suburban Plainsboro in Middlesex County. This eventual relocation creates a degree of uncertainty about how well positioned this applicant would be in the future to enhance minority and medically underserved access to elective angioplasty.

Princeton's projected annual volume of PCI cases places it twenty-second among the 22 applicants, making it less competitive in this regard than all other competing applicants. I find that approval of Princeton’s demonstration application would therefore not contribute to the timely completion of the demonstration project.

Princeton is one of six demonstration project applicants located in the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services. Princeton ranks fourth among the six applicants with respect to providing access to minority and medically underserved populations in their respective service areas and sixth in terms of projected PCI volume. I find that approval of Princeton would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying Princeton's application.

21 St. Peter's Medical Center 071218-12-01 Middlesex County

I find that there is an alternative elective angioplasty provider located within Middlesex County and the City of New Brunswick (i.e., Robert Wood Johnson University Hospital) and several alternative providers located in contiguous counties (Mercer and Monmouth counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing applicants, including applicants located elsewhere in Middlesex County.

I find that Robert Wood Johnson University Hospital is the recipient of 100 percent of St. Peter's Medical Center (St. Peter's) cardiac referrals, with 53.6 percent of that existing cardiac surgery center's angioplasty cases originating from the St. Peter's service area.

Access to medically underserved and minority populations in Middlesex County is less likely to be greatly improved by this applicant, since the applicant's service area is largely duplicative of that of the existing elective angioplasty provider located in the City of New Brunswick.

St. Peter's is one of six demonstration project applicants located in the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and St. Peter's ranks first among the six applicants as well as all other applicants with respect to the proximity to an existing elective PCI provider. I find that approval of St. Peter's would therefore not contribute to improved access to elective PCI services in comparison with other competing applicants.

For the above reasons, I am denying St. Peter's application.

22 Hunterdon Medical Center 071219-10-01 Hunterdon County

There are elective angioplasty providers in counties contiguous to Hunterdon County (Morris and Mercer counties), thereby limiting the applicant's ability to provide improved geographic access to this service to a greater extent than other competing applicants that are able to document enhanced access to medically underserved population groups in other regions in the State.

Projected annual angioplasty volume to achieve compliance with Atlantic C-PORT-E study minimum volume criteria or minimum State annual volume criteria, as set forth at N.J.A.C. 8:33E-2.3(d)1 and N.J.A.C. 8:33-3.11(e)6v., based on Hunterdon Medical Center's (Hunterdon) historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. Hunterdon's projected annual volume of PCI cases places it fourteenth among the 22 applicants, making it less competitive in this regard. Approval of Hunterdon's demonstration application would therefore not contribute to the timely completion of the demonstration project.

Hunterdon is one of six demonstration project applicants located in the New Brunswick hospital market area that the New Jersey Commission on Rationalizing Health Care Resources defined as one of eight relevant geographic areas. Within this hospital market area there is one alternative cardiac surgery center providing elective angioplasty services and Hunterdon ranks sixth among the six applicants with respect to providing access to minority and medically underserved populations in their respective service areas and fifth in terms of projected PCI volume. I find that approval of Hunterdon would therefore not contribute to either improved access or the timely completion of the demonstration project in comparison with other competing applicants.

For the above reasons, I am denying Hunterdon's application.

LICENSURE AND FAIR HEARING INFORMATION

Failure by Bayonne, Clara Maass, Community, Holy Name, JFK, Overlook, Raritan Bay, RWJ-Hamilton, Riverview, Somerset, Trinitas and Virtua – Marlton to satisfy the preceding conditions of approval may result in sanctions, including license suspension and monetary penalties, in accordance with N.J.S.A. 26:2H-1 and all applicable administrative rules. Acceptance of these conditions by each facility will be presumed, unless the facility's representative submits, within 30 days of the date of this letter, objections to the conditions. Should a facility submit an objection to the conditions, that facility's approval will be deemed suspended and the award will be reexamined in light of any specific objections. Objections to conditions should be made in writing, to:

John Calabria, Director

Department of Health and Senior Services
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, New Jersey 08625-0358.

Pursuant to N.J.S.A. 26:2H-9, Capital - Mercer, Chilton, Christ, Hunterdon, Monmouth, Mountainside, Ocean, Princeton, Saint Clare's – Denville, and St. Peter's are entitled to hearings at the Office of Administrative Law to contest the denial of their respective applications. Requests for such hearings should be made in writing within 30 days of receipt of this notice, and should be submitted to:

Ruth Charbonneau, Director
Department of Health and Senior Services
Office of Legal and Regulatory Affairs
P.O. Box 360, Room 805
Trenton, New Jersey 08625-0360,

Failure to submit a timely notice will negate the opportunity for such hearing(s).

The Department has determined that it is appropriate to license the seven existing C-PORT-E demonstration project hospitals, Bayonne, Holy Name, Raritan Bay, RWJ-Hamilton, Somerset, Trinitas, and Virtua - Marlton on an expedited basis. These seven demonstration hospital projects will be relicensed upon submission of a letter attesting the hospital's acceptance of the conditions contained in this letter and the hospital's continued compliance with all Departmental and C-PORT-E participation requirements. Such a letter shall be submitted, or objections to the conditions raised shall be submitted, within 30 days of the date of this letter in order for these demonstration project hospitals to continue in the C-PORT-E demonstration project. A new license shall be issued upon submission of this letter. The letter shall be submitted to:

John Calabria, Director
Department of Health and Senior Services
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, New Jersey 08625-0358.

The five new providers who are approved by this letter, Clara Maass, Community JFK, Overlook and Riverview, shall submit licensing applications to the Department and upon approval to participate in the C-PORT-E demonstration project a license shall be issued. The licensure process shall be completed within six months of the date of this letter.

If you have any questions concerning these matters, please do not hesitate to telephone Mr. John A. Calabria, Director, Office of Certificate of Need and Healthcare Facility Licensure, at (609) 292-8773.

Sincerely,

Heather Howard
Commissioner

c: State Health Planning Board
John Calabria

ENDNOTES

1. States that allow elective angioplasty without back-up surgery on site: Arizona, Colorado, Iowa, Illinois, Indiana, Maine, Minnesota, Missouri, North Carolina, New Hampshire, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

2. N.J.A.C. 8:33-1.3.

3. 18 New Jersey Cardiac Surgery Centers perform elective angioplasty: AtlantiCare Regional Medical Center, Cooper Health System, Deborah Heart & Lung Center, Englewood Hospital and Medical Center, Hackensack University Medical Center, Jersey City Medical Center, Jersey Shore Medical Center, Morristown Memorial Hospital, Newark Beth Israel Medical Center, Our Lady of Lourdes Medical Center, Robert Wood Johnson University Hospital – New Brunswick, Saint Barnabas Medical Center, St. Francis Medical Center, St. Joseph's Hospital and Medical Center, St. Mary's Hospital, St. Michael's Medical Center, UMDNJ/University Hospital, and The Society of Valley Hospital.

4. 39 N.J.R. 5316(b). Response to Comment 4.

5. The Atlantic C-PORT Trial, Elective Angioplasty Study, Manual of Operations," Version 2.5 (March 22, 2005), (Manual of Operations), as amended and supplemented;

6. Certificate Of Need And Acute Care Licensure "Notice Of Invitation For Certificate Of Need Applications For Participation In A Demonstration Project Pertaining To Elective Angioplasty Without Back-Up Surgery On-Site" 36 N.J.R. 4996(b), (Nov. 1, 2004).

7. Office of Certificate of Need and Healthcare Facility Licensure "Notice of Invitation for Certificate of Need Applications for Participation in Demonstration Projects Pertaining to Elective Angioplasty without Back-Up Surgery On-Site," 39 N.J.R. 4869(a), (Nov. 5, 2007).

8. As the Department's staff analysis of preliminary cardiac registry data indicated, statewide demand for cardiac surgery has been in continual decline, from a high of 11,678 cases in 2000 to 8,431 in 2007 (27.8 percent decline). Coronary angioplasty, on the other hand, had increased during that same period from 21,787 to 24,162 (10.9 percent increase). Prior to calendar year 2007, these divergent trends were expected to continue as angioplasty became the preferred treatment option over cardiac surgery. Subsequent to the staff's review, final unaudited cardiac registry data for calendar year 2007 became available. While the final unaudited data revealed no change in cardiac surgery volume, total

coronary angioplasty cases increased from 24,162 to 25,773, thereby representing an 18.3 percent increase since 2000.

The Department staff's review of preliminary New Jersey cardiac registry data for 2007 indicated that statewide angioplasty volume declined for the first time (24,162 angioplasty cases were performed in 2007 compared to 30,472 cases in 2006, representing a 20.7 percent decline since 2006). Similarly, the use of final unaudited cardiac registry data results in a decline of 15.4 percent in angioplasty cases for calendar year 2007 (based on 25,773 cases rather than 24,162). Diagnostic cardiac catheterization cases, which the staff reported as declining by 6.7 percent during this same one year period actually declined by 3.4 percent (74,714 cases in 2006 compared to 72,119 cases in 2007.) These revisions are caused by the need to provide the most recent data available for the CN review process at the same time that the Department's data collection effort was in the midst of major changes. Fortunately, the revisions are largely the result of the omission of primary angioplasty cases performed at the state's cardiac surgery centers, which only became reported separately in calendar year 2007. The final unaudited cardiac registry data still shows a decline in angioplasty and diagnostic catheterization cases in calendar year 2007, but the extent of the decline has been greatly reduced. As far as the 2007 data for the 22 CN demonstration project applicants under review, I find that there was virtually no impact. A single diagnostic catheterization case and 2 primary PCI cases were added to Christ Hospital's total and one primary PCI was added to both Overlook and Mountainside totals as a result of the use of the finalized unaudited 2007 data.

9. *JAMA.* 2002; 287:1943-1951.

10. Atlantic C-PORT-E Manual of Operations, Version 3.0, March 24, 2006, pp. 6 and 13.

11. Atlantic C-PORT-E Manual of Operations, Version 3.0, March 24, 2006, pp. 6 and 12.

12. Final Report. Commission On Rationalizing Healthcare Resources. (January 24, 2008). http://www.state.nj.us/health/rhc/finalreport/documents/entire_finalreport.pdf

13, Atlantic C-PORT-E Manual of Operations, Version 3.0, March 24, 2006, pp. 10 and 31.

14. Atlantic C-PORT-E protocol states it will employ a 3:1 randomization scheme. Ibid at p.6 and p.12.

15. 39 N.J.R. 5316(b). Response to comments 8 & 9.

16. The study protocol also states, “One important motivation is to sustain primary PCI [that is, the more commonly used term for PTCA] programs at hospitals without SOS [that is, cardiac surgery on site]. Primary PCI improves patient outcomes and reduces adverse events in patients with ST-segment elevation myocardial infarction (STEMI). Because most patients with STEMI present to hospitals without SOS, timely access to primary PCI and patient outcomes are improved by extension of primary PCI capability to hospitals without SOS. Sustaining stand-alone primary PCI programs can be difficult both financially and in terms of required human resources. The ability to perform elective PCI can help assure maintenance of these important programs and may refine expertise by increasing volume.” The Atlantic C-PORT-*E* Manual of Operations, Version 3.0, March 24, 2006, p. 4.