TO: State Health Planning Board

FROM: Department of Health and Senior Services Staff

DATE: July 7, 2008

SUBJECT: Recommendations Regarding Certificate of Need Applications for Participation in a Demonstration Project Pertaining to Elective Angioplasty without Back-up Surgery On-Site

Department of Health and Senior Services (Department) staff have completed their review of the certificate of need applications for participation in a demonstration project pertaining to elective angioplasty without back-up surgery on-site that have been submitted in response to a call issued on November 5, 2007 (39 N.J.R. 4869(a)). As the text of the call notice indicated, the Department published the call notice:

…inviting certificate of need applications on a full review basis for participation in a planned multi-state demonstration project to assess the safety, quality and cost of elective angioplasty offered at community hospitals that do not also offer cardiac surgery services on-site. The Department is taking this action as part of a broader cardiovascular health initiative. The purpose of the elective angioplasty demonstration is to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of the comparative safety and efficacy of elective angioplasty in hospitals with and without on-site coronary artery bypass graft (CABG) surgical back-up. In order to assure that the demonstration yields sound data and evidence, the Department is specifically inviting 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).
The call notice was issued in response to a decision of the New Jersey Supreme Court that 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 trial. *Cooper University Hospital v. Jacobs, 191 N.J. 125 (2007).*

Prior to the issuance of the call notice, and in response to the decision of the New Jersey Supreme Court (*Cooper University Hospital v. Jacobs, 191 N.J. 125 (2007)*), the Department established certificate of need 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).

As the Department indicated in the original certificate of need review process for elective PCI demonstration projects that took place in 2005, a number of New Jersey hospitals had expressed very strong interest in offering elective angioplasty services, independent of offering cardiac surgery at the same site, due to the trends for cardiac surgery and coronary angioplasty or PCI moving in opposite directions in that period of time (2000 – 2004). Demand for cardiac surgery had been steadily declining statewide, from a high of 11,678 cases in 2000 to 9,874 in 2004 (15% decline), while angioplasty had grown during that same period from 21,787 to 27,357 (26% increase). This trend was projected to continue as angioplasty continued to become the preferred treatment option over cardiac surgery and has in fact done so prior to calendar year 2007.

A review of preliminary New Jersey cardiac registry data for 2007 indicates that cardiac surgery did indeed continue to decline statewide (8,431 cases or 14.6% since 2004), but statewide angioplasty volume also declined for the first time (24,162 angioplasty cases were performed in 2007, representing an 11.7% decline since 2004 or an annual decline of 3.9% over the past three years). Since statewide PCI or angioplasty volume did not decline until 2007, however, the actual decline in angioplasty volume between 2006 and 2007 was 6,310 cases or 20.7 percent. Diagnostic cardiac catheterization cases also exhibited a decline of 6.7% during this same one year period (74,714 cases in 2006 compared to 69,724 cases in 2007.) It must be emphasized that there have been years during the past two decades that have exhibited a decline, and that have been followed by continued growth. It would be inappropriate and premature to project long-term trends based on a single calendar year (2007), particularly considering the fact that annualizing first quarter 2008 statewide PCI data (6,306 cases) would result in a 4.4 percent increase over 2007. The decline in PCI during 2007 can be attributed, at least in part, to recent evidence from clinical trials that PCI may not be superior to optimal medical therapy in reducing the risk of death or myocardial infarction.1

Also, in September 2006 the FDA issued an initial statement related to concerns about adverse events related to drug eluting stents (DES). The FDA’s Circulatory System Devices Advisory Panel met on December 7 and 8, 2006 and agreed that off-label use of DES, (i.e., use on more complex patients and more coronary lesions compared to those patients studied to support initial marketing) is associated with an increased risk of stent thrombosis, death or MI compared to on-label use.2 Yet a more recent study concludes that for patients with

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multi-vessel disease, coronary artery bypass graft (CABG) surgery continues to be associated with lower mortality, MI and repeat vascularization than does PCI with drug eluting stents. In making its recommendations, therefore, the Department must take into account clinical changes and trends in cardiac interventions that may impact future utilization of cardiac resources in the State. The preceding rationale supports the staff recommendation that the number of demonstration sites remain at nine and not expand to 12 as permitted at N.J.A.C. 8:33-3.11(e)2 and (e)7.

The Department has relied to a great extent in developing its standards for hospital-based cardiac services on the clinical guidelines developed by the American College of Cardiology/American Heart Association (ACC/AHA). For example, when the ACC/AHA guidelines concerning primary angioplasty were modified after review of newer research comparing the safety of these services in hospitals with and without cardiac surgery on-site, the Department subsequently modified its Certificate of Need rules to uncouple primary angioplasty from on-site cardiac surgery. A total of 21 states were permitting elective PCI without cardiac surgery backup when New Jersey hospitals began enrolling patients in the demonstration project last year. In addition, New York State has begun its own pilot program, and the Commonwealth of Massachusetts has established an independent study, both on the same subject. The demonstration project requires informed patient consent and includes elaborate patient safety mechanisms to minimize the potential for poor outcomes.

New Jersey, as a densely populated and congested State, has much to offer and much to gain from participating in the study. The State offers a sizable number of patients to contribute to the study, which will help the study to achieve its volume goals more efficiently. At the same time, the demonstration project results would inform the Department'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 study results would inform policymakers with respect to future rationalization of health care resource allocation, particularly for cardiac services, that may enhance access to care for the people of New Jersey. Finally, the participation of New Jersey hospitals in the study would 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 in the ordinary course.

At present, there continues to be little research data available on the issue of the comparative safety of elective angioplasty at hospitals without on-site cardiac surgery back-up. At the March 2008 ACC/SCAI Summit the results of the largest clinical study to compare PCI programs with and without on-site cardiac surgery backup were released. The study titled “Percutaneous Coronary Interventions in Facilities without On-Site Cardiac Surgery: A Report from the National Cardiovascular Data Registry (NCDR)” found that PCI can be performed safely and successfully in medical centers without on-site cardiac surgery backup, provided programs are well-organized, highly skilled and committed to quality. The authors warn that “the results of this study should not be used to encourage wild expansion of more

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off-site PCI programs; rather they should be used to confirm the appropriateness of this strategy for programs that have made a strong commitment to excellent organization and data submission for quality assurance.” Thus, the Department believes that this demonstration project, in partnership with Johns Hopkins Medical Institutions, will contribute significantly towards data collection associated with this study. It is also important to note that at their June 6, 2007 meeting a majority of the members of the Cardiovascular Health Advisory Panel (CHAP) “supported the concept that the Department should be able to support well-designed clinical investigation regarding delivery of health services.” They supported the use of the Commissioner’s authority to revise the elective angioplasty regulations “to allow the study to continue in an uninterrupted fashion.” Without further research findings on this issue there is insufficient scientific basis on which the ACC/AHA could consider changing the current guidelines for elective angioplasty or the Department could consider changing its certificate of need and licensure policy despite the widespread interest of hospitals, cardiologists and consumers in making this service widely available in community hospitals. It is also necessary to note that the Department will continue its monitoring of all cardiac facilities and services, including those participating as demonstration projects. This routine monitoring includes a review of facility and physician volumes and other quality measures. The Department works closely with facilities who fail to comply with these criteria so as to improve performance. Facilities who fail to comply are placed on conditional licensure and are required 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.

The ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention states that “as with many dynamic areas in interventional cardiology, these recommendations (i.e., elective PCI programs without onsite surgery) may be subject to revision as clinical data and experience increase. It is in the context of contributing to the effort to create an objective basis for assessing the safety and efficacy of a policy to expand elective angioplasty to community hospitals that the Department originally decided to participate in a rigorous, multi-state study of this issue. That same context continues to motivate the Department’s determination to support New Jersey hospital participation in the Atlantic C-PORT-E study. As stated in response to previous comments, New Jersey hospital participation in the Atlantic C-PORT-E trial is intended to facilitate scientifically rigorous collection and analysis of data that will contribute significantly to the evidence base nationally on the issue of comparative safety and efficacy of elective PCI in hospitals with and without on-site coronary artery bypass graft surgical back-up. New Jersey joins eight other states in this study.

Thomas Aversano, M.D., Associate Professor of Medicine, John 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. The research findings underlying this publication contributed significantly to the revised ACC/AHA guidelines concerning primary or emergency angioplasty.

Dr. Aversano subsequently designed a follow-up study, The Atlantic C-PORT Trial-Elective Angioplasty Study, (Atlantic C-Port-E), which 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 and major adverse cardiovascular events nine months after index PCI.”

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.

Atlantic C-PORT-E is designed as a prospective, randomized trial, which is considered the most 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 program hospital or a cardiac surgery center. This type of design minimizes the potential for selection bias to influence the study outcomes.

The 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 program to secure approval from its Institutional Review Board for its participation in this research project involving human subjects. As of the date of preparation of the State Staff recommendation, Dr. Aversano advised that the following states were permitting participation 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.

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 protocol’s requirements for participating hospitals. 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. To promote the scientific rigor of the Atlantic C-PORT-E study in meeting its enrollment requirements, case volume of applicants is significant.

Consistent with the requirements of the certificate of need call notice (39 N.J.R. 4869(a)), the Certificate of Need Application and Review Process (N.J.A.C. 8:33) and the cardiac services rule (N.J.A.C. 8:33E), the overarching goal of the staff review of the applications was to assure access to safe and effective cardiac services, especially for the medically underserved and minority populations, while at the same time ensuring the safety, efficacy and quality of

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6 Ibid. p.6
angioplasty services throughout New Jersey. Accordingly, these staff recommendations have been prepared in accordance with the call notice, the statutory criteria contained in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1.1 et seq.), as amended, the regulatory criteria for cardiac services as set forth at N.J.A.C. 8:33E, the certificate of need administrative process rules as set forth at N.J.A.C. 8:33, the specific elective angioplasty demonstration project rules set forth at N.J.A.C. 8:33-3.11(e), and the cardiac service licensing rules as set forth at N.J.A.C. 8:43G-7. Department staff have also reviewed the historic and most recently available statewide and region-specific cardiac service utilization data, cardiac-related death rates, and population/demographic data; studies concerning quality in cardiac service delivery and its relationship to volume, as well as studies concerning the impact of new technologies, specifically drug-eluting stents, on the need for angioplasty and cardiac surgery. Finally, Department staff carefully reviewed the information provided in each application which sought to demonstrate each applicant’s ability to participate in the Atlantic C-PORT-E study.

CERTIFICATE OF NEED ELIGIBILITY

As specified in the call notice and N.J.A.C. 8:33-3.11(e)4, eligibility to submit a certificate of need application to become a participant in the demonstration project is limited to licensed general hospitals that:
1. Are not currently licensed to perform cardiac surgery;
2. Have signed one or more agreements with one or more New Jersey-licensed cardiac surgery centers indicating that the New Jersey-licensed cardiac surgery center is willing to participate in the Atlantic C-PORT-E trial, including collecting and submitting data to the principal investigator, as the center with on-site surgery to which some of the applicant hospital's patients will be randomly assigned for elective PCI; and
3. Are licensed to provide primary PCI services; or have an approved but not yet implemented certificate of need to provide primary PCI services.

A maximum of twelve elective angioplasty demonstration project applications may be approved by the Department (N.J.A.C. 8:33-3.11(e)2 and 7).

DEMONSTRATION PROJECT APPLICANTS

<table>
<thead>
<tr>
<th>Hospital</th>
<th>County</th>
<th>CN Number</th>
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<tbody>
<tr>
<td>1. Holy Name Hospital*</td>
<td>Bergen</td>
<td>071213-02-01</td>
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<tr>
<td>2. Bayonne Hospital*</td>
<td>Hudson</td>
<td>071226-09-01</td>
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<tr>
<td>3. Christ Hospital</td>
<td>Hudson</td>
<td>071223-09-01</td>
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<tr>
<td>4. Clara Maass Medical Center</td>
<td>Essex</td>
<td>071217-07-01</td>
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<tr>
<td>5. Mountainside Hospital</td>
<td>Essex</td>
<td>071228-07-01</td>
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<tr>
<td>6. Muhlenberg Regional Medical Center*</td>
<td>Union</td>
<td>071214-20-01</td>
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<tr>
<td>7. Overlook Hospital</td>
<td>Union</td>
<td>071212-20-01</td>
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<tr>
<td>8. Trinitas Hospital – Williamson Street*</td>
<td>Union</td>
<td>071209-20-01</td>
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<tr>
<td>9. Chilton Memorial Hospital</td>
<td>Morris</td>
<td>071225-14-01</td>
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10. St. Clare’s Hospital – Denville  Morris  071210-14-01
11. Raritan Bay Medical Center*  Middlesex  071207-12-01
12. St. Peter’s Medical Center  Middlesex  071218-12-01
13. JFK Medical Center  Middlesex  071215-12-01
14. Somerset Medical Center*  Somerset  071222-18-01
15. Hunterdon Medical Center  Hunterdon  071219-10-01
16. University Medical Center@ Princeton  Mercer  071208-11-01
17. Robert Wood Johnson Med. Ctr. @ Hamilton*  Mercer  071227-11-01
18. Capital Health System – Mercer  Mercer  071211-11-01
19. Riverview Medical Center  Monmouth  071221-13-01
20. Monmouth Medical Center*  Monmouth  071216-13-01
21. Community Medical Center  Ocean  071220-15-01
22. Ocean Medical Center – Brick  Ocean  071231-15-01
23. Virtua-West Jersey Hospital – Marlton*  Burlington  071230-03-01
24. Virtua – Burlington (Mount Holly)  Burlington  071229-03-01
25. South Jersey Hospital  Cumberland  071224-06-01

* Currently licensed Elective PCI Demonstration Site

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 (39 N.J.R. 4869(a)) 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 applicants 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.

Review Criteria

In accordance with the certificate of need call for the demonstration projects (39 N.J.R. 4869(a)) and the elective angioplasty demonstration project criteria set forth at N.J.A.C. 8:33-3.11(e), the Department staff considered the criteria listed below, in addition to compliance with applicable criteria and standards as set forth in the statute (N.J.S.A. 26.2H-1 et seq.) and administrative rules at N.J.A.C. 8:33, N.J.A.C. 8:33E and N.J.A.C. 8:43G-7, in selecting the potential for a maximum of twelve approved applications from among the 22 remaining competing applicants.

With respect to the statutory certificate of need (CN) review criteria, N.J.S.A. 26:2H-8 provides for the issuance of a certificate of need 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, the participants in the CN review process must take into consideration a) the availability of facilities or services which 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 manpower in the several professional disciplines, and f) such other factors as may be established by regulation.

With respect to the latter consideration, the Department staff evaluation is required to consider whether each applicant has sufficiently documented the ability to satisfy 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 trial 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).

The Department staff evaluation is 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)).

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

The Department staff reviewed each applicant’s historical and current licensure track record of compliance with licensure requirements for the existing cardiac services provided by each applicant (i.e., cardiac catheterization, primary PCI, elective PCI, if applicable). Staff also
reviewed the applicant’s historical case volume and outcomes such as death in lab, death in hospital, and all in lab complications of each applicant’s diagnostic cardiac catheterization, primary angioplasty and, if applicable, elective angioplasty programs. The number of interventional cardiologists on each applicant’s staff and their respective performance in terms of interventional case volume was also reviewed. The results of these individual laboratory evaluations can be found in the individual CN project summaries that have been prepared by Department staff.

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

The Department staff reviewed the availability of elective angioplasty services in each applicant’s proposed service area. The 22 demonstration applicants are located in 12 of the State’s 21 counties. A total of five of the 22 demonstration applicants are located in three counties (i.e., 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 three counties and are in need of elective angioplasty would be required to leave the county to receive the service. Two of these three counties (i.e., Somerset, Union) currently have elective angioplasty demonstration site participants in the Atlantic C-PORT-E study and these sites were seeking continued participation in this review process. One of these applicants, Muhlenberg Regional Medical Center, one of two participants in the Atlantic C-PORT-E study that are located in Union County, withdrew its elective PCI demonstration project application when a certificate of need application to close the hospital was filed with the Department.

In addition, Department staff considered each applicant’s location based on the eight defined geographic areas (“hospital market areas”) which the New Jersey Commission on Rationalizing Health Care Resources determined to be reflective of actual patient utilization of hospitals. The remaining 22 elective angioplasty demonstration project 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.

The hospital market areas for the 22 elective angioplasty demonstration projects are indicated below, together with the identification of the cardiac surgery centers that are located within each hospital market area:

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<tr>
<th>Hospital</th>
<th>Hospital Market Area</th>
<th>Cardiac Surgery Center(s)</th>
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<tbody>
<tr>
<td>Bayonne Medical Center</td>
<td>Newark/Jersey City</td>
<td>Jersey City Medical Center</td>
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<tr>
<td>Christ Hospital</td>
<td>Newark/Jersey City</td>
<td>University Medical Center</td>
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<tr>
<td>Clara Maass Medical Center</td>
<td>Newark/Jersey City</td>
<td>St. Michael’s Med. Center</td>
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<td>Mountainside Hospital</td>
<td>Newark/Jersey City</td>
<td>Newark Beth Israel Med. Ctr.</td>
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<tr>
<td>Trinitas Hospital</td>
<td>Newark/Jersey City</td>
<td>St. Barnabas Medical Center</td>
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<tr>
<td>Chilton Memorial Hospital</td>
<td>Hackensack, Ridgewood and Paterson</td>
<td>Hackensack Medical Center</td>
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<tr>
<td>Holy Name Hospital</td>
<td>Hackensack, Ridgewood and Paterson</td>
<td>Englewood Hospital</td>
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<td>Overlook Hospital</td>
<td>Morristown</td>
<td>Morristown Memorial Hosp.</td>
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<tr>
<td>Saint Clare's Hospital/Denville Campus</td>
<td>Morristown</td>
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<tr>
<td>Hunterdon Medical Center</td>
<td>New Brunswick</td>
<td>RWJ University Hospital</td>
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<td>JFK Medical Center</td>
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<td>Raritan Bay Medical Center</td>
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<td>Saint Peter's University Hospital</td>
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<td>Somerset Medical Center</td>
<td>New Brunswick</td>
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<tr>
<td>University Medical Center at Princeton</td>
<td>New Brunswick</td>
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<td>Community Medical Center</td>
<td>Toms River</td>
<td>Jersey Shore Medical Center</td>
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<td>Monmouth Medical Center</td>
<td>Toms River</td>
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<td>Ocean Medical Center</td>
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<td>Riverview Medical Center</td>
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<td>Capital Health System at Mercer</td>
<td>Trenton</td>
<td>St. Francis Medical Center</td>
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<td>RWJ Univ. Hosp./Hamilton</td>
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<td>Virtua-West Jersey Hospital Marlton</td>
<td>Camden</td>
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<td>Our Lady of Lourdes Med. Ctr.</td>
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<td>Deborah Heart &amp; Lung Center</td>
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Potential to increase access to care for minorities and the medically underserved (N.J.A.C. 8:33-3.11(e)7iii.); and
The 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 demonstration applicants. The Department compared the racial composition of each applicant’s defined service area to the racial composition of the patient population receiving diagnostic cardiac catheterization services at the applicant’s facility. Ideally, the applicant’s patient population would reasonably reflect the composition of its service area. The applicant’s payer mix for diagnostic cardiac catheterization was also reviewed, though no service area comparison was available.

Importantly, the Department assessed the impact of the recommended approvals on existing providers, including existing regional cardiac surgery centers. In this review, the Department considered participation in a time-limited demonstration project and its impact to increase access to care for minorities and the medically underserved and determined, based on the overall PCI volume performed at all regional cardiac surgery centers, that there would not be a substantial negative impact on volume due to these recommendations. (See Appendix A for a listing of regional cardiac surgery centers.)

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 applicants and evaluated potential elective angioplasty case volume based on the Atlantic C-PORT-Elective Angioplasty Manual of Operations projected diagnostic cardiac catheterization to elective angioplasty conversion rate of 30 percent. The rankings, based on the average of three years (i.e., 2005 to 2007) of cardiac catheterization program volume (with the most recent calendar year of primary PCI added), are as follows:

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</tr>
</thead>
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<tr>
<td>1. Community Medical Center</td>
<td>1275</td>
<td>1096</td>
<td>1052</td>
<td>3423</td>
<td>342</td>
<td>257</td>
<td>+122 = 379</td>
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</tr>
<tr>
<td>2. Somerset Medical Center*</td>
<td>980</td>
<td>967</td>
<td>829</td>
<td>2776</td>
<td>278</td>
<td>208</td>
<td>+78 = 286</td>
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<td>3. Raritan Bay Medical Center*</td>
<td>834</td>
<td>1048</td>
<td>972</td>
<td>2854</td>
<td>285</td>
<td>214</td>
<td>+55 = 269</td>
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<td>4. Ocean Medical Center – Brick</td>
<td>804</td>
<td>721</td>
<td>712</td>
<td>2237</td>
<td>224</td>
<td>168</td>
<td>+77 = 245</td>
<td></td>
</tr>
<tr>
<td>5. Robert Wood Johnson M. C. @ Hamilton*</td>
<td>795</td>
<td>826</td>
<td>747</td>
<td>2368</td>
<td>237</td>
<td>178</td>
<td>+53 = 231</td>
<td></td>
</tr>
<tr>
<td>6. Virtua-West Jersey Hospital – Marlton*</td>
<td>749</td>
<td>972</td>
<td>798</td>
<td>2519</td>
<td>252</td>
<td>189</td>
<td>+35 = 224</td>
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<tr>
<td>7. St. Peter’s Medical Center</td>
<td>590</td>
<td>988</td>
<td>982</td>
<td>2560</td>
<td>256</td>
<td>192</td>
<td>+27 = 219</td>
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<tr>
<td>8. JFK Medical Center</td>
<td>716</td>
<td>662</td>
<td>688</td>
<td>2066</td>
<td>207</td>
<td>155</td>
<td>+58 = 213</td>
<td></td>
</tr>
<tr>
<td>9. Trinitas Hospital – Williamson Street*</td>
<td>563</td>
<td>629</td>
<td>685</td>
<td>1877</td>
<td>188</td>
<td>141</td>
<td>+58 = 199</td>
<td></td>
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<tr>
<td>10. Overlook Hospital</td>
<td>546</td>
<td>444</td>
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<td>1390</td>
<td>139</td>
<td>104</td>
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<tr>
<td>11. St. Clare’s Medical Center – Denville</td>
<td>530</td>
<td>466</td>
<td>423</td>
<td>1419</td>
<td>142</td>
<td>106</td>
<td>+61 = 167</td>
<td></td>
</tr>
<tr>
<td>12. Clara Maass Medical Center</td>
<td>428</td>
<td>622</td>
<td>627</td>
<td>1677</td>
<td>168</td>
<td>126</td>
<td>+37 = 163</td>
<td></td>
</tr>
</tbody>
</table>

- 11 -
13. Chilton Memorial Hospital    372       466      452|    1291   129      97   + 63 = 160
14. Hunterdon Medical Center    473       493      485|    1565  157    132   + 21 = 159
15. Bayonne Hospital*           506       667      592|    1765   177    132   + 45 = 145
16. Riverview Medical Center    584       496      485|    1565  157    132   + 21 = 159
17. Holy Name Hospital*         437       477      412|    1326     133    100   + 45 = 139
18. Monmouth Medical Center*    541       512      474|    1527   153    115   + 26 = 136
19. Capital Health System – Mercer  410     486      434|    1330   133    100   + 39 = 139
20. Christ Hospital             522       526     419 |    1467    147    110   + 26 = 136
21. Mountainside Hospital       481       397      362|    1240 124      93   + 33 = 126
22. University Medical Center @ Princeton  440     394      397|    1231         123      92   + 28 = 120

Note: Applicants may also have provided additional volume projections based on the assumptions of increased referrals, patient preferences, demographics and population increases which are not reflected in the above table.

* Existing Atlantic C-PORT-E demonstration project.

**Actual demonstration project elective angioplasty case volume.**

Since New Jersey currently has nine elective PCI demonstration projects participating in the Atlantic C-PORT-E Study, staff included a review of enrollment activity during the most recent 2007 calendar year, comparing actual patient enrollment in the study with the 30 percent projection figure that has been used to project potential elective PCI candidates at demonstration project sites. As the results of the first full year of New Jersey hospital participation in C-PORT-E indicate below, the 30% projection figure is resulting in an overestimate of likely elective PCI candidates, since slightly less than 20% of diagnostic cardiac catheterization patients at the nine demonstration projects qualified for, and were subsequently enrolled in, the Atlantic C-PORT-E Study.

### ATLANTIC C-PORT-E DEMONSTRATION PROJECTS
(2007 ACTUAL vs. PROJECTED ENROLLMENT)

<table>
<thead>
<tr>
<th>Hospital Demonstration Project</th>
<th>Actual Caths 2007</th>
<th>Projected E-PCI/yr. 2007 (30%)</th>
<th>Projected On-Site Randomized Cases (75%)</th>
<th>Actual C-PORT-E Enrolled 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Raritan Bay Medical Center</td>
<td>972</td>
<td>292</td>
<td>219</td>
<td>173</td>
</tr>
<tr>
<td>3. Somerset Medical Center</td>
<td>829</td>
<td>249</td>
<td>187</td>
<td>120</td>
</tr>
<tr>
<td>4. Robert Wood Johnson M. C. @ Hamilton</td>
<td>747</td>
<td>224</td>
<td>168</td>
<td>80</td>
</tr>
<tr>
<td>5. Virtua-West Jersey Hospital – Marlton</td>
<td>798</td>
<td>239</td>
<td>180</td>
<td>78</td>
</tr>
<tr>
<td>6. Trinitas Hospital – Williamson Street</td>
<td>685</td>
<td>206</td>
<td>154</td>
<td>72</td>
</tr>
<tr>
<td>7. Bayonne Hospital</td>
<td>592</td>
<td>178</td>
<td>133</td>
<td>124</td>
</tr>
<tr>
<td>8. Monmouth Medical Center</td>
<td>474</td>
<td>142</td>
<td>107</td>
<td>60</td>
</tr>
<tr>
<td>9. Holy Name Hospital</td>
<td>412</td>
<td>124</td>
<td>93</td>
<td>62</td>
</tr>
</tbody>
</table>

| Totals                        | 6,114             | 1,836                            | 1,377                                    | 901*                        |
1,201 total enrollees = 901 + 300 randomized to a cardiac surgery center, resulting in 19.6% enrollment (of the 6,114 total patients catheterized) in the Atlantic C-PORT-E trial in 2007.

In evaluating the above review criteria (N.J.A.C. 8:33-3.11(e)7i.-iv.), Department staff have sought to balance the relative role of the competitive review criteria, since few of the 22 potential demonstration project applicants were able to sustain high rankings in each of the evaluative areas of quality, volume, and geographic and medically underserved access considerations. An applicant, for example, might rank comparatively lower in volume, but rank comparatively higher in enhancing minority or medically underserved access. In short, each applicant’s documentation of compliance with the full range of statutory and regulatory criteria were weighed by Department staff to derive the following recommendations.

**STAFF RECOMMENDATIONS – Rationale**

1. **VIRTUA-WEST JERSEY HOSP. – MARLTON 071230-03-01 BURLINGTON COUNTY**

DHSS Staff Recommendation: Approval with Conditions

**Rationale**

1. 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 trial 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).

2. 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.

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

4. 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 high projected demonstration project angioplasty case volume.

5. 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.

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

7. 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.

8. 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 exceeds its provision of cardiac services to minority and medically underserved populations in its service area and ranks sixth of all applicants in terms of projected PCI volume. Approval of Virtua-Marlton would therefore contribute to both improved access and the timely completion of the research study in comparison with other competing applicants.

Conditions
1. Virtua-Marlton's license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.

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
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.

2. MONMOUTH MEDICAL CENTER
   071216-13-01
   MONMOUTH COUNTY

DHSS Staff Recommendation: Denial

Rationale
1. 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.
2. Monmouth has provided the thirteenth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing relatively low projected demonstration project elective angioplasty case volume that would not 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 not contribute toward a timely completion of the research study in comparison to other competing applicants.
3. Actual annual elective and primary angioplasty volume for Monmouth, which amounted to only 86 total PCI cases in 2007, is also 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 continuance of Monmouth as an elective angioplasty demonstration project would not contribute to the timely completion of the research study in comparison to other competing applicants.
4. 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 Monmouth ranks first among the four 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.

3. RIVERVIEW MEDICAL CENTER
   071221-13-01
   MONMOUTH COUNTY

DHSS Staff Recommendation: Denial

Rationale
1. 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.

2. Riverview Medical Center (Riverview) has provided the twelfth largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during the past three calendar years (2005-2007), thereby providing relatively low projected demonstration project elective angioplasty case volume that would not 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 not contribute toward a timely completion of the research study in comparison to other competing applicants.

3. 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. Approval of Riverview would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.

4. OCEAN MEDICAL CENTER – BRICK 071231-15-01 OCEAN COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. Access to medically underserved and minority populations cannot be expected to be greatly improved, since the applicant’s service area does not contain significant minority and medically underserved populations.

2. The applicant is the second ranked demonstration applicant located in Ocean County (seventh 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.

3. 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 by medically underserved and minority populations residing within their respective service areas.

4. 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. Approval of Ocean Medical Center - Brick would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.
Rationale
1. Community Medical Center (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 trial 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).
2. Participating Community Medical Center 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.
3. Community has been a licensed primary PCI service provider since June 29, 2005.
4. Community has provided the largest volume of diagnostic cardiac catheterization cases of all of the demonstration applicants during each of the past two calendar years (18% higher than the second highest volume demonstration applicant), 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 research study.
5. Community is located in Ocean County where this is no elective angioplasty provider currently licensed.
6. Community 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 Community ranks first in terms of projected PCI volume. Approval of Community would therefore contribute to the timely completion of the research study in comparison with other competing applicants.
Conditions

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 review for compliance with State licensure standards at the end of the first and second years.

4. Community shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.

5. 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.

6. 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.

7. 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.

6. ROBERT WOOD JOHNSON M. C. AT HAMILTON 071227-11-01 MERCER COUNTY

DHSS Staff Recommendation: Approval with Conditions

Rationale

1. 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 trial 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).

2. 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.

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

4. 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.

5. RWJ/Hamilton has successfully implemented an elective angioplasty demonstration project and has contributed valuable performance data as part of a scientifically rigorous multi-state research 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).

6. 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.

7. 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 RWJ/Hamilton ranks second among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas and first in terms of projected PCI volume. Approval of RWJ/Hamilton would therefore contribute to both improved access and the timely completion of the research study in comparison with other competing applicants.

Conditions
1. Robert Wood Johnson Medical Center at Hamilton's (RWJ/Hamilton) license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.

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.

7. CAPITAL HEALTH SYSTEM – MERCER 071211-11-01 MERCER COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. There is an alternative elective angioplasty provider located within Mercer County and Trenton City (i.e., 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.

2. 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.

3. The applicant 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.

4. 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 Capital Health System - Mercer's (Capital-Mercer) 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 twentieth among the
22 applicants, making it less competitive in this regard. Approval of Capital-Mercer’s demonstration application would therefore not contribute to the timely completion of the research study.

5. 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 and Capital-Mercer ranks first among the two 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. Approval of Capital-Mercer would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.

8. UNIVERSITY MEDICAL CENTER AT PRINCETON 071208-11-01 MERCER COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. There is an alternative elective angioplasty provider located within Mercer County and Trenton City (i.e., 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.

2. 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 duplicative of that of the existing elective angioplasty provider located in Trenton City.

3. The applicant 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.

4. University Medical Center at 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. Approval of University of Princeton’s demonstration application would therefore not contribute to the timely completion of the research study.

5. University Medical Center at 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 and University Medical Center of 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. Approval of University Medical Center at Princeton would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.
DHSS Staff Recommendation: Denial

Rationale

1. 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.

2. Access to medically underserved and minority populations in Middlesex 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 the City of New Brunswick.

3. 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. Approval of St. Peter’s would therefore not contribute to improved access to elective PCI services in comparison with other competing applicants.

DHSS Staff Recommendation: Approval with Conditions

Rationale

1. 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 trial 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).
2. Participating Somerset Medical Center 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.

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

4. 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 research study.

5. Somerset is located in a county where this is no elective angioplasty provider.

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

7. 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. Approval of Somerset would therefore contribute to the timely completion of the research study in comparison with other competing applicants.

**Conditions**

1. Somerset's license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.

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.

11. RARITAN BAY MEDICAL CENTER 071207-12-01 MIDDLESEX COUNTY

DHSS Staff Recommendation: Approval with Conditions

Rationale
1. 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 trial 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).

2. Participating Raritan Bay Medical Center 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.

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

4. 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 research study.

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

6. 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.

7. 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. Approval of Raritan Bay would therefore contribute to improved access and the timely completion of the research study in comparison with other competing applicants.

**Conditions**

1. Raritan Bay Medical Center's (Raritan Bay) license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.

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.

**12. JFK MEDICAL CENTER 071215-12-01 MIDDLESEX COUNTY**

**DHSS Staff Recommendation:** Approval with Conditions

**Rationale**

1. 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 trial 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).

2. 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.

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

4. 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.

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

6. 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.

7. JFK Medical Center (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 and 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, approval of JFK would contribute to both improved access and the timely completion of the research study in comparison with other competing applicants.

**Conditions**

1. JFK Medical Center (JFK) shall obtain approval from its Institutional Review Board and approval for participation in the Atlantic C-PORT-E research study prior to being licensed for the elective angioplasty service by the Department.

2. JFK shall be licensed by the Department as an elective angioplasty demonstration project provider prior to the one year expiration date of the certificate of need 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 review for compliance with State licensure standards at the end of the first and second years.

4. JFK shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.

5. 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.

6. 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.

7. 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.

13. HUNTERDON MEDICAL CENTER 071219-10-01 HUNTERDON COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. 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.

2. 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 fifteenth 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 research study.

3. 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. Approval of Hunterdon would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.

14. OVERLOOK HOSPITAL 071212-20-01 UNION COUNTY

DHSS Staff Recommendation: Approval with Conditions

Rationale

1. 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 trial 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).

2. For the most part, participating Overlook Hospital 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.

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

4. 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.

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

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

7. 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.

8. 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. Approval of Overlook would therefore contribute to improved access and timely completion of the research study in comparison with other competing applicants.

**Conditions**

1. Overlook’ Hospital’s (Overlook) license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.
2. Overlook shall perform elective angioplasty only on patients who consent to and subsequently are enrolled in the Atlantic C-PORT-E Study.
3. 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.
4. 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.
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 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.

15. **ST. CLARE’S HOSPITAL – DENVILLE** 071210-14-01 MORRIS COUNTY

**DHSS Staff Recommendation:** Denial

**Rationale**
1. There is an 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.

2. 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 St. Clare’s Hospital historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. Approval of St. Clare’s Hospital’s demonstration application would therefore not contribute to the timely completion of the research study.

3. 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. Approval of St. Clare’s would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.

16. MOUNTAINSIDE HOSPITAL 071228-07-01 ESSEX COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. 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. Approval of Mountainside would therefore not contribute to the timely completion of the research study.

2. The applicant’s projected demonstration project elective angioplasty case volume, the twenty-first largest average 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.

3. Mountainside Hospital 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.

4. Mountainside 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, however, there are five alternative cardiac surgery centers providing elective angioplasty services and Mountainside Hospital 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. Approval of Mountainside would therefore not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.

17. BAYONNE HOSPITAL 071226-09-01 HUDSON COUNTY

DHSS Staff Recommendation: Approval with conditions

Rationale
1. Bayonne has successfully implemented an elective angioplasty demonstration project and has contributed valuable performance data as part of a scientifically rigorous multi-state research study 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).
2. Bayonne has been a licensed primary PCI service provider since January 17, 2006.
3. Hudson County is densely populated and has a very high percentage of minority and medically underserved residents. In 2006, 38.8 percent of Bayonne’s diagnostic cardiac catheterization patients were minorities, demonstrating that this applicant has a strong track record in enhancing access to care.
4. 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 trial 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).
5. 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 participant demonstration projects.

Conditions
1. Bayonne’s license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the each year of participation in the Atlantic C-PORT-E Study.
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, 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 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 30 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 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.

18. CHRIST HOSPITAL 071223-09-01 HUDSON COUNTY

DHSS Staff Recommendation: Denial

Rationale
1. There is an 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.

2. 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 Christ Hospital’s historical catheterization laboratory performance, would be less likely to occur in comparison to other competing demonstration applicants. Approval of Christ Hospital’s demonstration application would therefore not contribute to the timely completion of the research study.

3. Access to medically underserved and minority populations in Hudson County is less likely to be expected to be greatly improved by this applicant, since the applicant’s service areas is, for the most part, duplicative of the existing elective angioplasty provider that is located in Jersey City.

4. 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, however, there are five alternative cardiac surgery centers providing elective
angioplasty services and Christ Hospital ranks fourth in terms of projected PCI volume.
Approval of Christ Hospital’s demonstration application would therefore not contribute
to the timely completion of the research study in comparison with other competing
applicants.

19. CLARA MAASS MEDICAL CENTER  071217-07-01  ESSEX COUNTY

DHSS Staff Recommendation: Denial

Rationale
1. There are three elective angioplasty providers located within Essex County (i.e.,
Newark Beth Israel Medical Center, St. Michael’s Medical Center, University Hospital)
and numerous other alternative providers in contiguous counties (Bergen, Passaic and
Morris counties), thereby limiting Clara Maass’ ability to provide improved geographic
access to this service to a greater extent than other competing demonstration
applicants.
2. 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 less likely to occur in comparison to other competing
demonstration applicants. Approval of Clara Maass would therefore not contribute to
the timely completion of the research study.
3. Clara Maass 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 with higher levels of minority and
medically underserved populations and have documented the ability to provide its
current cardiac services to these population groups.
4. Clara Maass Medical Center 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 Clara Maass Medical Center 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. Approval of Clara Maass would therefore not contribute to
either improved access or the timely completion of the research study in comparison
with other competing applicants.

20. TRINITAS HOSPITAL – WILLIAMSON STREET 071209-20-01  UNION COUNTY

DHSS Staff Recommendation: Approval with Conditions

Rationale
1. 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 trial 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).

2. For the most part, participating Trinitas Hospital 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.

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

4. 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.

5. Trinitas is located in Union County, where there is no elective angioplasty provider currently licensed other than itself and Muhlenberg Regional Medical Center, located in Plainfield, which has withdrawn its application, and thereby Trinitas’ approval would continue to improve geographic access to this service.

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

7. 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.

8. Trinitas 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, however, there are five alternative cardiac surgery centers providing elective angioplasty services and Trinitas Hospital ranks second 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 research study in comparison with other competing applicants.

Conditions
1. Trinitas' license to perform elective angioplasty shall not exceed three years, and shall be subject to review for compliance with State licensure standards at the end of the first and second years.

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.

21. HOLY NAME HOSPITAL 071213-02-01 BERGEN COUNTY

DHSS Staff Recommendation: Denial

Rationale

1. There are three elective angioplasty providers located within Bergen County (i.e., Hackensack Medical Center, Englewood Medical Center, Valley Hospital) as well as other alternative providers in contiguous counties (Passaic, Hudson and Essex counties), thereby limiting Holy Name’s ability to provide improved geographic access to this service for the residents of its service area to a greater extent than other competing demonstration applicants in other regions of the State.

2. Projected annual angioplasty volume for Holy Name would not be sufficient to achieve compliance with Atlantic C-PORT-E study minimum volume criterion or the minimum State annual volume criteria, as set forth at N.J.A.C. 8:33E-2.3(d)1, and would therefore not contribute to the timely completion of the research study.

3. Holy Name would not improve access to minority and medically underserved populations to a greater extent than other competing demonstration applicants that are located in other regions of the State and have documented their ability to enhance access to minority and medically underserved populations in their service area.

4. Holy Name’s ability to enroll sufficient elective PCI candidates to achieve State and Atlantic C-PORT-E minimum annual volume requirements has not been documented.
by the applicant’s actual level of patient enrollment to date, with only 62 patients enrolled in Atlantic C-PORT-E and receiving their intervention at Holy Name during CY 2007.

5. 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 there are five alternative cardiac surgery centers providing elective angioplasty services and Holy Name ranks first (least distant) of the two applicants with respect to proximity to an alternative elective PCI provider and fourth among the 22 applicants in this category.

22. CHILTON MEMORIAL HOSPITAL 071225-14-01 MORRIS COUNTY

DHSS Staff Recommendation: Denial

Rationale
1. There is an 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.

2. 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 Chilton’s historical catheterization laboratory performance, would be far less likely to occur in comparison to other competing demonstration applicants. Approval of Chilton’s demonstration application would therefore not contribute to the timely completion of the research study.

3. Chilton Memorial Hospital is one of two applicants located in the Hackensack, Ridgewood and 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 there are five alternative cardiac surgery centers providing elective angioplasty services and Chilton Memorial Hospital ranks second among the two applicants with respect to providing access to minority and medically underserved populations in their respective service areas and first in terms of projected PCI volume. Approval of Chilton however would not contribute to either improved access or the timely completion of the research study in comparison with other competing applicants.
## Appendix A

### New Jersey Hospitals Providing Regional Cardiac Surgery Services

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper Hosp./University Medical Center</td>
<td>One Cooper Plaza, Camden, NJ 08103</td>
</tr>
<tr>
<td>Robert Wood Johnson University Hospital</td>
<td>180 Somerset Street, New Brunswick, NJ 08901</td>
</tr>
<tr>
<td>Deborah Heart and Lung Center</td>
<td>Trenton Road, Browns Mills, NJ 08015</td>
</tr>
<tr>
<td>Morristown Memorial Hospital</td>
<td>100 Madison Avenue, Morristown, NJ 07960</td>
</tr>
<tr>
<td>Newark Beth Israel Medical Center</td>
<td>201 Lyons Avenue, Newark, NJ 07112</td>
</tr>
<tr>
<td>Newark Beth Israel Medical Center at St. Barnabas Medical Center</td>
<td>94 Old Short Hills Road, Livingston, New Jersey 07039</td>
</tr>
<tr>
<td>Hackensack University Medical Center</td>
<td>30 Prospect Avenue, Hackensack, NJ 07601</td>
</tr>
<tr>
<td>Our Lady of Lourdes Medical Center</td>
<td>1600 Haddon Avenue, Camden, NJ 08103</td>
</tr>
<tr>
<td>St. Michael’s Medical Center</td>
<td>268 Dr. M. Luther King, Jr., Blvd, Newark, NJ 07102</td>
</tr>
<tr>
<td>St. Mary’s Hospital/Passaic</td>
<td>350 Boulevard, Passaic, NJ 07055</td>
</tr>
<tr>
<td>Jersey Shore Medical Center</td>
<td>1945 Corlies Avenue, Neptune, NJ 07753</td>
</tr>
<tr>
<td>Saint Joseph’s Hospital and Medical Center</td>
<td>703 Main Street, Paterson, NJ 07503</td>
</tr>
<tr>
<td>University Hospital/UMDNJ</td>
<td>100 Bergen Street, Newark, NJ 07103</td>
</tr>
<tr>
<td>The Valley Hospital</td>
<td>Linwood and North Van Dien Avenues, Ridgewood, NJ 07451</td>
</tr>
<tr>
<td>Englewood Hospital and Medical Center</td>
<td>350 Engle Street, Englewood, New Jersey 07631</td>
</tr>
<tr>
<td>St. Francis Medical Center</td>
<td>601 Hamilton Avenue, Trenton, New Jersey 08629</td>
</tr>
<tr>
<td>Atlantic City Medical Center – Mainland Division</td>
<td>Jimmie Leeds Road, Pomona, N.J. 08240</td>
</tr>
<tr>
<td>Jersey City Medical Center</td>
<td>355 Grand Street, Jersey City, New Jersey 07304</td>
</tr>
</tbody>
</table>